VA National Formulary

VISN 20

Formulary Status: Non-formulary

Sort Order: Generic Name

Formulary by Class | Formulary by Generic Name | Non-formulary by Class | Non-formulary by Generic Name

VA Class	Generic Name	Brand Name	Restriction Text	Formulary Status
MS190	ABATACEPT INJ	ORENCIA	RESTRICTION(S) AND OTHER INFORMATION: National PBM Drug Criteria for Use ABATACEPT (ORENCIA) Consider ABATACEPT As MONOTHERAPY if: - Documented contraindications, intolerance (toxicity) and/or suboptimal response to an adequate trial of MTX; AND - Documented contraindications, intolerance and/or suboptimal response to > 1 DMARDS at standard target dose (unless significant toxicity limited the dose tolerated), regardless of whether they were prescribed sequentially or in combination: oral/injectable gold, hydroxychloroquine, sulfasalazine, penicillamine, azathioprine, leflunomide, etanercept, infliximab, adalimumab, anakinra) As COMBINATION THERAPY with MTX or DMARDs OTHER THAN TNF-aINHIBITORS (i.e., etanercept, infliximab, adalimumab) if: - Documented suboptimal response with full or maximally tolerated doses of MTX or DMARDs OTHER THAN TNF-a INHIBITORS (i.e., etanercept, infliximab, adalimumab) CRITERIA FOR ELIGIBILITY*: * Each patient's risk versus benefit should be carefully considered before initiating therapy (or continuing therapy) in instances where safety and efficacy have not been established (See Table 4). Choice of therapy should be based on physician discretion and clinical judgment. 1. Diagnosis of RA as defined by the American College of	NON-FORMULARY

			Rheumatology (ACR); AND 2. Active RA despite full and adequate treatment with > 1 standard DMARDs at standard or maximally tolerated dose; AND 3. Baseline monitoring parameters within normal limits (See Table 5). CRITERIA FOR EXCLUSION: 1. MTX naive - If a patient has failed to demonstrate an adequate response to a single DMARD other than MTX, MTX should be initiated with doses up to 25mg/week (as tolerated) for at least 3 months, with or without other DMARDs; OR 2. If a patient has previously achieved remission on a given DMARD, he or she should be restarted on this previously effective DMARD prior to use of abatacept;OR 3. Contraindications to abatacept. (See Table 3). CRITERIA FOR CONTINUATION: After initiation of an agent, adequate response with decreased disease activity such as improvement in severity of affected joints or resolution of flares/decrease in flares within 2-24 weeks based on clinical judgment and quantitative measurements, including: 1. Improvement in validated quantitative measures of response such as the Health Assessment Questionnaire (HAQ), visual analog scales (VAS), Likert scales, joint tenderness and/or swelling, and laboratory data (ESR, CRP); AND 2. Improvement in the DAS score > 1.2; OR 3. Achievement of a DAS28 score of < 3.2; OR 4. > 20% improvement according to ACR 20% response criteria 5. Monitoring parameters at follow-up MUST be within normal limits (See Table 5).

			CRITERIA FOR WITHDRAWAL OF THERAPY: 1. Inefficacy - Inadequate response (despite confirmed compliance) within 2-24 weeks after starting treatment at the recommended dosing schedule (See Table 2); OR 2. Loss of efficacy/unacceptable disease activity after 3 consecutive months of maximum therapy despite confirmed compliance (i.e., Repetitive flares; progressive joint damage); OR 3. Development of drug-related toxicity or adverse events (See Tables 6 and 7). MAP/PBM August 2006; VISN 20 P&T Committee June 2007 see: [paste entire URL into browser] http://vaww.pbm.va.gov/criteria/Criteria%20for%20Use%20for%20Leflunomide%20and%20Biologic%20DMARDs.pdf Date Added: Date(s) Discussed: July 20, 2007	
AD100	ACAMPROSATE CA 333MG EC TAB	CAMPRAL	VA National and VISN 20 Criteria for Non-formulary Use of Acamprosate The initial prescription may be written for a 30 days supply with a maximum of two refills. If the patient has established a substantial reduction in alcohol use within 90 days, then long-term treatment with multiple refills may be authorized. Inclusion Criteria: All three following criteria MUST be met for acamprosate to be prescribed: 1 A current DSM-IV diagnosis of alcohol dependence	NON-FORMULARY

			2 Treatment with acamprosate should be part of a comprehensive management program that includes a psychosocial component therapy 3 Prior to initiation, the patient has established at least 4 days of abstinence with no more than mild alcohol withdrawal symptoms (e.g., as indicated by scores < 8 on the CIWA-Ar)* Comments: -Please note that to date, there are too few patients in the >65 age group to evaluate any differences in safety or effectiveness for geriatric patients compared to younger patients. -Please note that to date, there is no consistent evidence to suggest which types of patients may benefit from acamprosate. -There is insufficient evidence for the use of acamprosate in patients with concurrent illicit drug use. -The currently available evidence shows that acamprosate in combination with naltrexone is no better than naltrexone alone, although it is better than acamprosate alone in the outcomes of nonrelapse and first alcohol intake. Based on this limited evidence and expert opinion, the routine use of combination therapy is not recommended at this time, particularly in patients who have not first had a prior trial of naltrexone. *See http://www.detoxguideline.org/ or http://vaww.mentalhealth.med.va.gov/substance_use.shtm for online training in CIWA-Ar. Exclusion Criteria: * Patients not willing to receive concomitant	

			comprehensive management program that includes a psychosocial component therapy (e.g., psychosocial behavioral intervention focused on relapse prevention). * Severe renal impairment (CrCL < 30 mL/min) * Known hypersensitivity to acamprosate calcium or any of its components Comments: -Please Note: Acamprosate has not been established as effective for initiating abstinence in patients who have not done so prior to initiating drug therapy. -There are no adequate and well-controlled studies in pregnant women. Acamprosate should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus. If used among women of childbearing potential, consideration of an effective contraceptive method should be discussed and recommended. Dosing Comments: Therapy should start as soon as possible after abstinence has been established and should be combined with ongoing behavioral intervention focused on relapse prevention. * Initial dose is two 333mg acamprosate tablets (666mg) three times daily given orally. * For patients with moderate renal impairment (creatinine clearance of 30-50 mL/min), a starting dose of one 333 mg tablet orally taken three times daily is recommended. * For continued use, reassessment for efficacy is needed by	

documenting a substantial reduction in alcohol use in the patient's
medical record.

Comments:

-Although acamprosate may be given without regard to meals, dosing with
meals was employed during clinical trials and is suggested as an aid to
compliance in those patients who regularly eat three meals daily.

-The pharmacokinetics of acamprosate has not been evaluated in the
geriatric population.

-There are no clinical trials extending beyond 1 year with active drug
therapy to substantiate the long-term efficacy of acamprosate.

Monitoring/Patient Information

* Documentation in the medical chart of patient's adherence to an
ongoing comprehensive management program that includes a psychosocial
behavioral intervention for relapse prevention is recommended.

* Documentation in the medical chart of patient's self-report of
amount and pattern of any alcohol use is recommended.

* Patients, families and caregivers of patients being treated with
acamprosate should be alerted to the need to monitor patients for the
development of symptoms of depression or suicidal thinking, and to report
such symptoms to the patient's health care provider.

* Patients should be cautioned about operating hazardous machinery.

			including automobiles, until they are reasonably certain that acamprosate therapy does not affect their ability to engage in such activities. * Documentation in the medical chart of patient's medication adherence is recommended. * Patients should be advised to continue acamprosate as directed, even in the event of relapse and to discuss any alcohol use with their provider.** * Advise female patient(s) to notify caregiver immediately if become pregnant or intend to become pregnant during therapy. * Women of childbearing potential should be instructed to use an effective contraceptive method during therapy. Comments: -Because elderly patients are more likely to have reduced renal function, use care in dose selection; it may be useful to monitor renal function. -There are no clinical trials extending beyond 1 year of active drug therapy to substantiate the long-term efficacy of acamprosate. Patients taking acamprosate for longer than 1 year should be reassessed on a regular basis. -If patient has not achieved stable abstinence or clinically meaningful reduction in alcohol use after 6 weeks, assure medication adherence (e.g., with monitoring or involvement of significant other). ** If a patient relapses while taking acamprosate, the	

			decision to continue acamprosate should be made after weighing the potential risks versus benefits. Discontinuation Criteria * Patient is not actively engaged in a comprehensive management program that includes a psychosocial component while being prescribed acamprosate (e.g., psychosocial behavioral interventions focused on relapse prevention). * If patient has not initially established or was not able to maintain a significant reduction in ETOH use, consider discontinuing acamprosate therapy and reevaluate the treatment plan including a more intensive level of care. Comments: -There are insufficient data to establish with any certainty the superiority of one drug (i.e., naltrexone vs. acamprosate) over the other. (Grade C Recommendation) April 21, 2006 VISN 20 P&T Committee Date Added: Date(s) Discussed: April 21, 2006	
CV703	ACETAZOLAMIDE SA TAB/CAP	DIAMOX SA	Acetazolamide sustained action (SA) tablets and capsules are non-formulary, second-line to regular release tablets. June 2008 VISN 20 P&T Commitee	NON-FORMULARY
PH000	ACETIC ACID GLACIAL LIQUID	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
OT109	ACETIC ACID OTIC SOLN	VOSOL	Non-Formulary: no criteria for use	NON-FORMULARY

OT250	ACETIC ACID/HC/ OTIC SOLN	VOSUL HC	Non-Formulary: no criteria for use	NON-FORMULARY
CN701	ACETOPHENAZINE MALEATE ORAL	TINDAL	Non-Formulary: no criteria for use	NON-FORMULARY
XA199	ACTICOAT WOUND DRESSING	ACTICOAT	Acticoat is Non-Formulary, restricted to patients who have not responded adequately to other therapies, including alternative silver-based therapies. June 2004 VISN 20 P&T Committee	NON-FORMULARY
MS190	ADALIMUMAB INJ	HUMIRA	VISN 20 Adalimumab Non-Formulary Criteria for Use 1. Rheumatoid arthritis and psoriatic arthritis Adalimumab dosed at 40mg every other week and etanercept dosed at 25mg twice a week (or 50mg once a week) are equally available for patients who meet the following non-formulary criteria: a) ineffective therapeutic response or unable to tolerate at least four disease modifying anti-arthritic drugs (DMARDs), b) no active infection, and c) able to meet monitoring requirements Both adalumumab and etanercept remain non-formulary, restricted to use by VA staff rheumatologists or dermatologists or local VA facility equivalent, for the treatment of rheumatoid arthritis and psoriatic arthritis. If higher doses are needed for one agent, then patients should be converted to the other agent. 2. Crohn's Disease Adalimumab is restricted to Gastroenterology Service or local facility equivalent for use in the treatment of Crohn's Disease. Other formulary agents should be utilized for Crohn's Disease prior to either adalimumab or infliximab. August 2007 VISN 20 P&T Committee	NON-FORMULARY
DX201	ALBUMIN,MICROSPHERE HUMAN 5MG/UNT INJ	OPTISON	Human albumin microspheres (Optison) is restricted to the ECHO laboratory or local facility equivalent.	NON-FORMULARY
RE103	ALBUTEROL SULFATE 4MG SA TAB	PROVENTIL	Non-Formulary: no criteria for use	NON-FORMULARY
DE000	ALEFACEPT INJ	AMEVIVE	Alefacept, Etanercept, Efalizumab and Infliximab Non-Formulary Criteria for Psoriasis Use Alefacept, etanercept, efalizumab and infliximab are non-formulary for the treatment of severe psoriasis or psoriatic arthritis, restricted to physicians experienced in treating these indications such as Rheumatology, Dermatology, or local facility equivalent. Patients must meet all of the following criteria: 1. Patient is an adult > 18 years of age who has chronic (> 6 months) severe plaque psoriasis (for using any biologics) or psoriatic arthritis (for etanercept). Criteria for severe psoriasis: all four of the following: a. Disease is disabling or impairs the patient???s quality of life (self-reported), including the ability to work and activities of daily living AND b.	NON-FORMULARY

			Disease does not have a satisfactory response to treatments that have minimal risks AND c. The patient is willing to accept life-altering adverse effects to achieve less disease or no disease AND d. More than 10% of body surface is involved or other factors apply (patient???s attitude about disease; location of disease [e.g., face, hands, fingernails, feet, genitals]; symptoms [e.g., pain, tightness, bleeding, or severe itching]; arthralgias or arthritis). 2. Patient is a candidate for systemic antipsoriatic therapy or ultraviolet therapy, and has documented inaccessibility to ultraviolet therapy OR documented inadequate response, contraindication, intolerance, or hypersensitivity to methotrexate and, if available, ultraviolet therapy (PUVA or UVB) with or without oral retinoids (e.g., acitretin). 3. Patient has no contraindications to biologic therapy or other condition that would preclude the use of biologic agents. 4. No concurrent live or live-attenuated vaccines during therapy. 5. No concurrent immunosuppressive therapy except those used in the treatment of psoriasis. Ultraviolet therapy with or without retinoids is considered by experts to be safe to use with biologic agents, although published reports of such combination therapy are lacking at this time. Methotrexate is approved for concurrent use with etanercept and infliximab. Justification for any concurrent use of systemic or other immunosuppressive antipsoriatic therapy with biologic agents (such as for transitioning or potential additive effects in partial responders) should be clearly[Wed Nov 10 16:18:03 2010] dofile.pl: Wide character in print at c:\inetpub\wwwroot\reports\dofile.pl line 96. documented. Current prescribing information for the biologics advises against such combinations. Therefore, clinicians should weigh the potential risks and benefits before deciding to use concurrent ultraviolet, systemic, or other immunosuppressive therapy with biologics. VISN 20 P&T Committee November 19, 2004	
HS900	ALGIUCOSIDASE ALFA	LUMIZYME	NON-FORMULARY	NON-FORMULARY
CV400	ALISKEREN/VALSARTAN	VALTURNA	NON-FORMULARY	NON-FORMULARY
VT504	ALISKIREN ORAL TAB	TEKTURNA	Criteria for Non-formulary Use of Aliskiren (Tekturna) VHA Pharmacy Benefits Management Service and the Medical Advisory Panel Thiazide-type diuretics are the preferred first line agents for patients with uncomplicated hypertension (HTN). In addition, most	NON-FORMULARY

			patients will require more than one agent to control their blood pressure. Another class of medication [e.g., angiotensin-converting enzyme inhibitor (ACEI), long-acting CCB, or angiotensin II receptor antagonist (ARB) if ACEI intolerant] may be considered in patients who have a contraindication to or are inadequately controlled on a thiazide-type diuretic OR in patients who have an indication for an agent in another antihypertensive class (e.g., beta-blocker in a patient with prior-myocardial infarction or symptomatic coronary ischemia; ACEI and beta-blocker in patients with systolic heart failure). Therapy with other antihypertensive drug classes may be considered in patients who do not achieve an adequate clinical response despite therapy as recommended above. Due to the lack of published long-term outcome and safety data, aliskiren should be reserved for patients with HTN who do not tolerate or are not controlled on antihypertensive medications within the drug classes currently recommended as initial or alternative/supplemental drug therapy, as well as a reasonable trial of other supplemental drug therapy as per VHA/DoD Clinical Practice Guideline for Management of Hypertension in Primary Care (refer to www.oqp.med.va.gov), and that are available on the VA National Formulary (http://www.pbm.va.gov/NationalFormulary.aspx). The long-term efficacy and safety of combination therapy with aliskiren and an ACEI or ARB in the treatment of HTN compared to combination with an antihypertensive agent with a different mechanism of action is unknown; therefore, combination therapy with aliskiren and an ACEI or ARB is not advised at this time. In addition, the role of aliskiren as monotherapy or combination therapy with either an ACEI or ARB in influencing long-term outcomes for other indications (e.g., chronic kidney disease, heart failure) has not been determined. INCLUSION CRITERION FOR ALISKIREN (must fulfill the following to be eligible) 1) Treatment of hypertension in patients who have documented lack of adequate response or contraindication to, or inability to tolerate at least three antihypertensive agents on the VA National Formulary, one from each of the following drug classes: thiazide-type diuretic, ACEI (or ARB if an ACEI is indicated and the patient is ACEI intolerant*), long-acting calcium channel blocker. Since most patients will require more than one antihypertensive agent to control their blood pressure, if the patient's	

			blood pressure is not at goal despite therapy as recommended above, a trial of at least two additional antihypertensive agents listed on the VA National Formulary (e.g., reserpine, beta-adrenergic blocker, centrally acting agent, vasodilator, aldosterone antagonist, alpha-blocker) as supplemental therapy should be attempted prior to considering aliskiren *Unable to tolerate an ACEI due to cough or other non life-threatening reason. It is unknown if an ARB can be safely used as an alternative in patients who develop significant kidney dysfunction, hyperkalemia, or angioedema with an ACEI, as these adverse events have also occurred with the use of an ARB EXCLUSION CRITERIA (if ONE is applicable, patient is not eligible) 1) Pregnancy 2) Women of child-bearing potential not using adequate method of contraception after discussion of risk vs. benefit of treatment (refer to Monitoring) 3) History of angioedema with an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor antagonist (ARB) (while not specifically a contraindication, the risk vs. benefit of treatment in these patients should be taken into consideration) 4) Use for indications other than hypertension DOSING RECOMMENDATIONS The initial recommended total daily dose of aliskiren is 150 mg administered once daily The dose may be increased to a maximum of 300 mg once daily after two weeks if the blood pressure goal is not achieved It is recommended that aliskiren be administered at a consistent interval in relation to meals as a high fat meal decreased the absorption of the drug, the clinical significance of this is unknown MONITORING 1) Administration of medications that act at the renin-angiotensin-aldosterone system (RAAS) during pregnancy has resulted in neonatal morbidity and mortality; therefore, aliskiren should be discontinued as soon as possible after a patient becomes pregnant 2) As with other agents that act at the RAAS (e.g., ACEIs, ARBs, aldosterone antagonists), it is recommended that kidney function be monitored in patients where kidney function depends on the RAAS (e.g., renal artery stenosis, volume depletion, severe heart failure) and in patients with prior kidney dysfunction or diabetes mellitus (DM). Serum potassium should be monitored in patients receiving potassium-sparing diuretics, potassium supplements, or other medications that may increase serum potassium, and in patients with kidney impairment, DM, or heart failure. The frequency of	

			routine monitoring should take into consideration the patient's concomitant therapy and comorbid conditions 3) Symptomatic hypotension may occur in patients who may be sodium or volume depleted (e.g., in patients receiving diuretic therapy) upon initial therapy with aliskiren; it is recommended to correct the volume depletion prior to starting aliskiren, otherwise therapy should be initiated under close medical supervision 4) Aliskiren should be used with caution in the following patients: those with greater than moderate kidney dysfunction (defined as serum creatinine > 1.7 mg/dL for women and > 2.0 mg/dL for men, or estimated Glomerular Filtration Rate < 30 mL/min), on dialysis, with a history of nephrotic syndrome or renovascular HTN; as these patients were not included in the clinical trials 5) It has been reported that the blood concentrations of furosemide are significantly reduced when given in combination with aliskiren; therefore, the clinical effects of furosemide may be decreased after initiation of aliskiren RECOMMENDATIONS FOR DISCONTINUATION 1) Patient does not experience an improvement in blood pressure control 2) Patient experiences a significant drug related adverse event February 2008 VISN 20 P&T Committee	
CV400	ALISKIREN/HYDROCHLOROTHIAZIDE ORAL	TEKTURNA	Non-Formulary: no criteria for use	NON-FORMULARY
DE900	ALOEPLEX TOPICAL GEL	ALOEPLEX	Restricted to radiation oncology	NON-FORMULARY
RE900	ALPHA1-PROTEINASE INHIBITOR HUMAN	GLASSIA	NON-FORMULARY	NON-FORMULARY
XX000	ALPROSTADIL/PAPAVERINE INJ	BIMIX	Due to the lack of published data to support bi-mix use and limited patient population, alprostadil/papaverine bi-mix injection is non-formulary, restricted to patients failing alprostadil injection.	NON-FORMULARY
DE450	ALUMINUM HYDROXYCHLORIDE LOTION	N/A	Non-Formulary: no criteria for use	NON-FORMULARY

AN900	ALUMTUZUMAB INJ	CAMPATH	Alemtuzumab (Campath)is non-formulary, restricted to National VA criteria, which are: Restricted to VA Hematology/Oncology physicians for patients who meet the following three criteria: (1) Patients with (A) B-cell chronic lymphocytic leukemia who have been treated with alkylating agents and failed* fludarabine OR (B) patients with T-cell prolymphocytic leukemia (2) patients are not known to have Type I hypersensitivity or anaphylaxis to murine proteins or any other component of the drug product (3) patients do not have an active systemic infection or underlying immunodeficiency (e.g., HIV) other than CLL-induced immunodeficiency. *Fludarabine failure is defined as failure to achieve a Complete Response (CR) or a Partial Response (PR) after receiving fludarabine 25mg/m2 IV daily for 5 days repeated every 4 weeks OR relapse <6 months after achieving a CR or PR with fludarabine	NON-FORMULARY

GA900	ALVIMOPAN CAP,ORAL	ENTEREG	Alvimopan (Entereg)National Criteria for Nonformulary Use 10 April 2009 FDA-approved indication: acceleration of time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis in patients greater than 18 years of age Exclusion Criteria If ANY criterion below is met, then the patient should NOT receive alvimopan. O Hypersensitivity to alvimopan or product components. O Chronic opioid use for 1 week or greater prior to procedure O Severe hepatic impairment (Child-Pugh C) or End Stage Renal Disease O Epidural anesthesia is scheduled to be used during surgery O Complete Bowel Obstruction O Recent treatment with alvimopan in current episode of care (No studies evaluated safety and efficacy of more than one treatment course.) O Situations where pre-operative dose cannot be administered O Inflammatory Bowel Disease O Patients scheduled for total abdominal hysterectomy, total colectomy, ileostomy, or colostomy O Any non-FDA approved indication (E.A.S.E. programO see Entereg Ordering Instructions and VAMC Registration Form) Inclusion Criteria All of the following (AO C) must be fulfilled in order to meet criteria. A. Undergoing partial large or small bowel resection surgery B. Intravenous postoperative opioid pain management is planned C. A post-operative plan including encouraged mobility, removal of the NGT within one day of surgery, and early re-introduction of liquids and solid foods is planned ** Particular consideration should be given to patients considered at risk for prolonged post operative ileus (PPOI) a. Prior occurrence of PPOI after any surgical procedure. b. Anticipation of extensive (over 2 hours) adhesiolysis associated with a small or large bowel resection. c. Significant en bloc resection of intra-abdominal organs including large or small bowel. Discontinuation Criteria O Maximum of 15 doses allowed O Maximum of 7 days or until hospital discharge O Return of bowel function (i.e., bowel movement) Refills: No refills allowed Dosing (No adjustments necessary for mild-moderate renal or hepatic disorder) 12 mg orally twice daily, with first dose administered 30 minutes to 5 hours prior to surgery (max. 2 doses per day) in April 2009 VISN 20 P&T Cmte minutes.	NON-FORMULARY

AN700	AMIFOSTINE INJ	ETHYOL	Amifostine (Ethyol)is restricted to radiation oncology to decrease the incidence of acute and late xerostomia in patients undergoing radiation therapy in the head and neck region and for the reduction of cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer or non-small cell lung cancer.	NON-FORMULARY
CV704	AMILORIDE ORAL	MIDAMOR	Non-Formulary: no criteria for use	NON-FORMULARY
RS202	AMLODIPINE/VALSARTAN TAB	EXFORGE	Non-Formulary: no criteria for use	NON-FORMULARY
CV400	AMLODIPINE/VALSARTAN/HCTZ	ExForge-HCT	NON-FORMULARY	NON-FORMULARY
AM800	AMOXICILLIN EXTENDED RELEASE TABS	MOXATAG	Non-Formulary: no criteria for use	NON-FORMULARY
AM700	AMPHOTERICIN B LIPOSOME INJ	AMBISOME	Amphotericin B lipid complex (Abelcet) is formulary, restricted to: Infectious Disease and Bone Marrow Transplant Services for patients who meet one of the following criteria: (a) patients with pre-existing renal insufficiency (e.g., serum creatinine >2mg/dl or measured creatinine clearance 2.5mg/dl) while receiving conventional amphotericin B; (c) patients on concomitant nephrotoxic agents (e.g., cyclosporine, tacrolimus); (d) patients on dialysis for acute reversible renal failure; or (e) bone marrow or solid organ transplant patients with baseline serum creatinine > 1.5mg/dl. Amphotericin B liposome (Ambisome) is non-formulary, restricted to: Infectious Disease and Bone Marrow Transplant Services for patients who continue to have nephrotoxicity, severe infusion-related reactions (IRR) uncontrolled by premedications, or disseminated fungal infection to the brain while on amphotericin B lipid complex (Abelcet).	NON-FORMULARY

AM800	AMPRENAVIR ORAL	AGENERASE	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
AM700	ANADULAFUNGIN INJ	ERAXIS	Non-Formulary: no criteria for use	NON-FORMULARY
IM600	ANAKINRA INJ	KINERET	National PBM Drug Criteria for Use for ANAKINRA (KINERET) VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel Consider ANAKINRA As MONOTHERAPY if: - Documented contraindications, intolerance (toxicity) and/or suboptimal response to an adequate trial of MTX; AND - Documented contraindications, intolerance and/or suboptimal response to 1 or more standard DMARDS at standard target dose (unless significant toxicity limited the dose tolerated), regardless of whether they were prescribed sequentially or in combination: oral/injectable gold, hydroxychloroquine, sulfasalazine, penicillamine, azathioprine, leflunomide As COMBINATION THERAPY with MTX or DMARDs OTHER THAN TNF-??INHIBITORS (i.e., etanercept, infliximab, adalimumab)if: - Documented suboptimal response with full or maximally tolerated doses of MTX or DMARDs OTHER THAN TNF-??INHIBITORS (i.e., etanercept, infliximab, adalimumab) CRITERIA FOR ELIGIBILITY*: * Each patient's risk versus benefit should be carefully considered before initiating therapy (or continuing therapy) in instances where safety and efficacy have not been established (See Table 4). Choice of therapy should be based on physician discretion and clinical judgment. 1. Diagnosis of RA as defined by the American College of Rheumatology (ACR); AND 2. Active RA despite full and adequate treatment with 1 or more standard DMARDs at standard or maximally tolerated dose; AND 3. Baseline monitoring parameters within normal limits (See Table	NON-FORMULARY

			5). CRITERIA FOR EXCLUSION: 1. MTX naive - If a patient has failed to demonstrate an adequate response to a single DMARD other than MTX, MTX should be initiated with doses up to 25 mg/week (as tolerated) for at least 3 months, with or without other DMARDs; OR 2. If a patient has previously achieved remission on a given DMARD, he or she should be restarted on this previously effective DMARD prior to use of anakinra; OR 3. Contraindications to anakinra. (See Table 3). CRITERIA FOR CONTINUATION: After initiation of an agent, adequate response with decreased disease activity such as improvement in severity of affected joints or resolution of flares/decrease in flares within 8-12 weeks based on clinical judgment and quantitative measurements, including: 1. Improvement in validated quantitative measures of response such as the Health Assessment Questionnaire (HAQ), visual analog scales (VAS), Likert scales, joint tenderness and/or swelling, and laboratory data (ESR, CRP); AND 2. Improvement in the DAS score > 1.2; OR 3. Achievement of a DAS28 score of < 3.2; OR 4. > 20% improvement according to ACR 20% response criteria 5. Monitoring parameters at follow-up MUST be within normal limits (See Table 5). CRITERIA FOR WITHDRAWAL OF THERAPY: 1. Inefficacy - Inadequate response (despite confirmed compliance) within 8-12 weeks after starting treatment at the recommended dosing schedule (See Table 2); OR 2. Loss of efficacy/unacceptable disease activity - Ongoing disease activity after 3 consecutive months of maximum therapy despite confirmed compliance (i.e., Repetitive flares; progressive joint damage);OR 3. Development of drug-related toxicity or adverse events (See Tables 6 and 7). VISN 20 P&T Committee February 2009 http://vaww.apps.cmop.va.gov/PBMIntranetWEbSiteArchive/criteria/Criteria%20for%20Use%20for%20Leflunomide%20and%20Biologic%20DMARDs.pdf	
DE802	ANTHRALIN 0.25% TOP CREAM	ANTHRADERM	Non-Formulary: no criteria for use	NON-FORMULARY
IM400	ANTIRABIES SERUM,EQUINE INJ	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
DE650	ARFORMOTEROL SOLN,INHL	BROVANA	Non-Formulary: no criteria for use	NON-FORMULARY

BL100	ARGATROBAN INJ	ACOVA	Lepirudin (Refludan) is formulary, restricted to patients with HIT who require anticoagulation. Danaparoid (Orgaran) and argatroban (Acova) are non-formulary. Sept 2006 VISN 20 P&T Any of these agents can be ordered on a non-formulary basis with appropriate justification. The specific agent to use should be determined by the prescriber based on the individual patient. July 2001	NON-FORMULARY
AN900	ARSENIC TRIOXIDE 1MG/ML INJ	TRISENOX	Restricted to Hematology/Oncology for patients with relapsed acute promyelocytic leukemia who express the t(15;17) PML-RAR?? gene and have relapsed after standard treatment (i.e., ATRA, daunorubicin, and cytarabine). Patients with underlying cardiac arrhythmias should not receive arsenic trioxide.	NON-FORMULARY
AP101	ARTEMETHER/LUMEFANTRINE ORAL TAB	COARTEM	Non-Formulary: no criteria for use	NON-FORMULARY
BL900	ASENAPINE	SAPHRIS	NON-FORMULARY	NON-FORMULARY
AH900	ASTEMIZOLE ORAL	HISMANAL	Non-Formulary: no criteria for use	NON-FORMULARY
CN000	ATOMOXETINE ORAL	STRATTERA	Atomoxetine is non-formulary, restricted to the treatment of attention-deficit/hyperactivity disorder (ADHD) in patients who have not responded to or have contraindications to formulary alternatives methylphenidate and dextroamphetamine. July 2003	NON-FORMULARY
CV350	ATORVASTATIN	LIPITOR	NON-FORMULARY, CFU NON-FORMULARY, CFU	NON-FORMULARY
CV350	ATORVASTATIN ORAL	LIPITOR	Rosuvastatin is the preferred non-formulary high potency HMG for primary prevention of coronary events in patients with hypercholesterolemia. Atorvastatin may be used in place of rosuvastatin, simvastatin, lovastatin, or pravastatin for patients with inadequate LDL-C lowering response to a maximum dose of rosuvastatin, simvastatin or lovastatin, in patients not receiving potent CYP 3A4 inhibitors. September 2003 VISN 20 P&T Committee August 2007 - replaced fluvastatin with pravastatin. March 2008 - Rosuvastatin becomes 1st line NF HP HMG.	NON-FORMULARY
CN205	ATROPINE SO4/NEOSTIGMINE INJ	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
GA400	ATTAPULGITE ORAL (OTC)	KAOPECTATE	Non-Formulary: no criteria for use	NON-FORMULARY
NT400	AZELASTINE NASAL INHALATION	ASTELIN	Non-Formulary: no criteria for use	NON-FORMULARY
OP210	AZITHROMYCIN OPHTH SOLN	AZASITE	Non-Formulary: no criteria for use	NON-FORMULARY
AM119	AZTREONAM	CAYSTON	NON-FORMUALARY	NON-FORMULARY

OP201	BACITRACIN OPH OINT	AK-TRACIN	Non-Formulary: no criteria for use	NON-FORMULARY
DE102	BASIC FUCHIN /BORIC ACID/RESORCINOL/ACETONE TOP (O	N/A	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
DE900	BECAPLERMIN GEL	REGRANEX	Becaplermin (Regranex) Gel Nonformulary Criteria (Revised 10-08) VHA Pharmacy Benefits Management Services and the Medical Advisory Panel Becaplermin (Regranex) is to be used as an adjunct to, not a replacement for, good ulcer care including sharp debridement, non-weight bearing, standard of care moist dressing changes, and prevention and treatment of infection. Becaplermin gel is not approved for the treatment of pressure, venous stasis or other types of non-diabetic related ulcers. The decision to use becaplermin gel should be made by providers who are experienced in chronic care of recalcitrant ulcers (Vascular/wound clinics, plastic surgery clinics, podiatry clinics, etc.). FDA APPROVED INDICATION o For the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and possess an adequate blood supply. BOXED WARNING-MANUFACTURER LABEL An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of becaplermin gel in a post-marketing retrospective cohort study. Becaplermin gel should only be used when the benefits can be expected to outweigh the risks. Becaplermin gel should be used with caution in patients with known malignancy.1-3 EXCLUSION CRITERIA o Known hypersensitivity to any component of the product (e.g., parabens) o Known neoplasm(s) at the site of application INCLUSION CRITERIA: (All of the following criteria must be met for use of becaplermin gel) o Patients should have a recent glycosylated hemoglobin	NON-FORMULARY

			(hemoglobin A1c or HbA1c) less than 8. If not, active treatment to improve glycemic control, including referral to Endocrinology if appropriate, should be attempted. o Patients should be nonsmoking and if not, plans for smoking cessation should be initiated. o Classification of diabetic wound severity: (All wounds must be free from infection) o University of Texas: Diabetic ulcer classified as a grade 2 or 3; stage A (clean, non ischemic, non infected wounds penetrating to the tendon or capsule or into bone or joint). o Wagner: Grade 1 or 2 (partial/full thickness ulcer or probing to tendon or capsule) o The wound must have an adequate blood supply measured by oscillometry (at least 2 units), transcutaneous partial pressure of oxygen (TcPo2) >30 mm Hg, ankle-brachial index (ABI) >0.7, ankle systolic pressure >70 mm Hg, or toe pressure >30 mm Hg. o Identification and removal of the underlying etiology of the wound (e.g. poor fitting shoes, reinforce non-weight bearing, etc.) The provider will consult the appropriate department to evaluate the patient for the proper orthotic to maximize minimal to non-weight bearing of the affected area. o The wound must be free from infection. o If present, lower extremity edema should be treated. o The patient's nutritional status has been addressed for any protein and/or calorie malnutrition. o The patient must have failed standard therapy for at least 2 months (careful-frequent debridement, moist dressing changes and non-weight bearing). o Patient and provider are committed to 10 weeks of becaplermin gel. Maximum duration is 20 weeks. Ultimately, patients should be treated for the shortest duration possible for wound healing (limit to < 2 tubes, unless there are compelling reasons otherwise). o The benefits and risks of becaplermin gel have been discussed with the patient and their understanding of the benefits/risks is documented in the medical record. DOSAGE AND ADMINISTRATION The amount of becaplermin gel applied will vary depending upon the size of the ulcer. To calculate an adequate dose of becaplermin gel, measure the greatest length multiplied by the greatest width of the ulcer in inches or centimeters: To calculate the proper dose in inches (in): 0.65 g of becaplermin per inch Tube Size Formula 15 g tube Length (in) X Width (in) X 0.6 To calculate the proper dose in centimeters (cm): 0.25 g of becaplermin per centimeter Tube Size Formula 15 g tube Length (cm) X Width (cm) divide by 4 The calculated dose of becaplermin gel (in centimeters or	

			inches) should be squeezed out onto a clean surface (wax paper) in a linear fashion. The measured dose can be transferred from this clean surface using an applicator (tongue blade or cotton swab) and spread over the ulcer's surface. The dose of becaplermin gel should be applied only once a day and spread evenly over the surface of the ulcer to produce a thin continuous layer about 1/16 of an inch in thickness. The gel should then be covered with saline moistened gauze and a secondary dressing and left for approximately 12 hours. For the second dressing change of the day, the gel can be gently rinsed off using saline or water and a saline moistened dressing applied to the ulcer without reapplication of becaplermin gel. It should be left for the remaining 12 hours of the day. (Reinforce to patients that application of excessive becaplermin gel has not been shown to be of greater benefit in ulcer healing) [Sample monitoring sheet on last page of this document] RECOMMENDED MONITORING FOR ASSESSMENT OF RESPONSE TO TREATMENT o The provider must assess the ulcer, either in person or via telemedicine, on a weekly to biweekly basis to assess ulcer response and to determine need for further debridement. o Assessment of ulcer response and patient compliance with good ulcer care should be determined (non-weight bearing, no smoking, dressing changes, ability to properly apply becaplermin gel). o The provider must calculate a new amount of becaplermin gel to be applied at every visit. o If the ulcer does not decrease by approximately 30% in size after 10 weeks of therapy, continued treatment with becaplermin should be reassessed. Treatment with becaplermin gel should continue until the ulcer is completely healed or a maximum of 20 weeks. If the ulcer has not completely healed after 20 weeks, the benefits/risks of continued treatment with becaplermin gel should be reassessed. PATIENT EDUCATION o Patients and care providers must be educated regarding proper application, storage (must be refrigerated) and the potential benefits/risks of becaplermin gel. An assessment of their ability to properly apply becaplermin gel should be done. o Patients and care providers need to be educated on proper wound care including dressing changes not involving application of becaplermin gel (second dressing change of the day). They also need to be educated on the importance of non-weight bearing measures. WHEN TO DISCONTINUE TREATMENT o	

			Becaplermin gel should be discontinued if there is	
NT200	BECLOMETHASONE 42MCG 200D AQ/NASAL	BECONASE	Non-Formulary: no criteria for use	NON-FORMULARY
AN100	BENDAMUSTINE INJ	TREANDA	Non-Formulary: no criteria for use	NON-FORMULARY
RS300	BENZOCAINE 20/DOCUSATE NA 283MG MINI-ENEMA	THERAVAC	Restricted to Neurology Service or local equivalent	NON-FORMULARY
NT300	BENZOCAINE ORAL SPRAY 20%	HURRICANE	Benzocaine 20% oral spray is non-formulary at National, VISN and Local levels. All VISN 20 sites were directed to remove benzocaine oral spray from local inventories by 4/2006. February 2006 VISN 20 P&T Committee Minutes	NON-FORMULARY
AP300	BENZYL ALCOHOL 5% LOTION	ULESFIA	Non-Formulary: no criteria for use	NON-FORMULARY
OP210	BESIFLOXACIN 0.6% SUSP,OPH	BESIVANCE	Non-Formulary: no criteria for use	NON-FORMULARY
HS051	BETAMETHASONE SODIUM PHOSPHATE & B. ACETATE INJ	CELESTONE	Non-Formulary: no criteria for use	NON-FORMULARY
OP109	BIMATOPROST OPHTH SOLN	LUMIGAN	Latanoprost and bimatoprost are non formulary, restricted to patients who cannot be adequately treated with the first line ophthalmic prostaglandin, travoprost. Bimatoprost is 2nd line, latanoprost is 3rd line. August 2003 VISN 20 P&T Committee	NON-FORMULARY
XA000	BIO-GLUE	BIO-GLUE	Bio-Glue is formulary, restricted to use according to its FDA indication, intraoperative aortic dissection. Feb 2004	NON-FORMULARY
RS300	BISACODYL IN PEG RECTAL SUPPOSITORY	MAGIC BULLET	PEG bisacodyl suppository (Magic Bullet) is formulary, restricted to spinal cord injury patients. (HVO bisacodyl suppositories remain open formulary without restrictions and are available for all other patients.)	NON-FORMULARY
HS200	BISACODYL/PHOSPHO SODA KIT (TAB/SUPP/LIQUID)	N/A	Non-Formulary: no criteria for use	NON-FORMULARY

CV900	BOSENTAN ORAL TAB	TRACLEER	Bosentan is a vasodilating agent used for the treatment of pulmonary hypertension in patients with World Health Organization (WHO) CHF Class III or IV symptoms to improve exercise capacity and to slow the rate of clinical worsening. Bosentan has been reviewed at the national level and placed in a non-formulary status at the national and VISN levels. The national decision was based upon the potential misuse of this medication and cost considerations ($36,000 per year per patient). Guidelines for pulmonary hypertension are currently being developed at the national level. Bosentan is available only through the Tracleer Access Program to ensure adherence with recommended liver enzyme screens and pregnancy tests. The program is staffed with health professionals educated in the use of bosentan, provides product information, documents adverse advents, and facilitates the coordination of benefits. Dec 2002 VISN 20 P&T Committee	NON-FORMULARY
OP900	BOTULINUM TOXIN TYPE A 100U	BOTOX	Botulinum toxin type A is non-formulary, restricted to gastroenterology, otolaryngology, ophthalmology, physical medicine, rehab, and urology services. May 2007 VISN 20 P&T	NON-FORMULARY
MS900	BOTULINUM TOXIN TYPE B	MYOBLOC	Botulinum Toxin Type B (Myobloc) is non-formulary, but is available for the FDA-approved indication of use in patients who have Botulinum Toxin Type A-resistant cervical dystonia. June 2005 VISN 20 P&T	NON-FORMULARY
RE501	BPM 12 PHENYLPROPANOLAMINE 75MG SA TAB	DIMETAPP	Non-Formulary: no criteria for use	NON-FORMULARY
CV300	BRETYLIUM INJ	BRETYLOL	Restricted to Cardiology Service or local equivalent	NON-FORMULARY
CV300	BRIMONIDINE/TIMOLOL SOLN,OPH	COMBIGAN	Non-Formulary: no criteria for use	NON-FORMULARY
OP109	BRINZOLAMIDE 1% OPH SUSP	AZOPT	Dorzolamide (Trusopt) is formulary, restricted to Ophthalmology/Eye Clinic or local facility equivalent as second line therapy. Brinzolamide (Azopt) is non-formulary, restricted to Ophthalmology/Eye Clinic or local facility equivalent. August 2007	NON-FORMULARY
AU900	BROMOCRIPTINE MESYLATE	CYCLOSET	NON-FORMULARY	NON-FORMULARY
RE501	BROMPHENIRAMINE 12MG PPA 75MG SA TAB	DIMETAPP	Non-Formulary: no criteria for use	NON-FORMULARY

RE000	BUDESONIDE EC ORAL CAPSULE	ENTOCORT EC	Oral budesonide is non-formulary, restricted to Gastroenterology or local facility equivalent according to the following criteria: a. Initial CDAI score 200-300, or initial CDAI score >300 with documented intolerance to conventional corticosteroid-related effects; and b. Involvement of the ileum and/or ascending colon, not the distal colon; and c. Budesonide may be used to treat an active flare associated with Crohn???s disease for eight weeks, with an additional eight weeks of therapy after reassessment for relapse; and d. Patients must be closely monitored for corticosteroid-associated effects and the need for therapy discontinuation should be reviewed if adverse events are observed. October 15 VISN 20 P&T Committee	NON-FORMULARY
BL900	C1 INHIBITOR	BERINERT	Non-Formulary	NON-FORMULARY
BL900	C1 INHIBITOR & ECALLANTIDE	BERINERT, CINRYZE, KALBITOR	NON-FORMULARY, RESTRICTED TO CFU	NON-FORMULARY
AN900	CABAZITAXEL	JEVTANA	NON-FORMULARY	NON-FORMULARY
AU900	CABERGOLINE ORAL	DOSTINEX	Cabergoline is Non-Formulary, restricted to patients with hyperprolactinemia who have not responded to or cannot tolerate bromocriptine. Sept 2008 VISN 20 P&T Committee	NON-FORMULARY
DE101	CADEXOMER IODINE 0.9% GEL,TOP	IODOSORB		NON-FORMULARY
VT501	CALCIFEDIOL ORAL	CALDEROL	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
IM600	CANAKINUMAB INJ	ILARIS	Non-Formulary: no criteria for use	NON-FORMULARY
CV805	CANDESARTAN ORAL	ATACAND	Angiotensin II Receptor Antagonist Criteria for Use in Veteran Patients I. Recommendations for Patients with Heart Failure (HF) - Valsartan Patients with systolic HF should be maximized on therapy with agents such as an angiotensin-converting enzyme inhibitor (ACEI),	NON-FORMULARY

			beta-adrenergic blocker, diuretic, and aldosterone antagonist, as indicated. Criteria for Angiotensin II Receptor Antagonist: Patient with systolic HF* (or HF/evidence of systolic dysfunction after acute MI) who is intolerant to an ACEI** Combination therapy with an ACEI (at optimal dose) and an angiotensin II receptor antagonist may be considered in patients with systolic HF*. However, due to conflicting data as to whether combination therapy of an AIIRA and ACEI, with or without a beta-adrenergic blocker, is of overall benefit in patients with systolic HF*, it is recommended that cardiology consultation or suitable alternative mechanism be established to evaluate the appropriateness of combination therapy based on the patient's clinical status and concomitant medications (note: combination therapy in patients with HF/evidence of systolic dysfunction after acute MI is not routinely recommended.) II. Recommendations for Patients with Diabetes Mellitus (DM) and Kidney Disease - Losartan Standard therapy for patients with DM and kidney disease includes treatment with an ACEI. As treatment with an angiotensin II receptor antagonist has been shown to reduce the combined endpoint of increasing sCr, end-stage renal diseases (ESRD), and death in patients with type 2 DM and nephropathy with hypertension (HTN) and/or on antihypertensive medications, an angiotensin II receptor antagonist may be considered as another treatment option in this patient population. Combination therapy with an ACEI and angiotensin II receptor antagonist in patients with nondiabetic kidney disease with persistent proteinuria or microalbuminuria**** may be considered, although national treatment guidelines recommend the benefits be confirmed in other trials with a larger patient population. Criteria for Angiotensin II Receptor Antagonist: Patient with type 2 DM and nephropathy*** with HTN (or receiving antihypertensive medication) who is intolerant to an ACEI** National treatment guidelines have also recommended an angiotensin II receptor antagonist in patients with DM and kidney disease or nondiabetic kidney disease with proteinuria or microalbuminuriad who are intolerant to an ACEIb. Use of an angiotensin II receptor antagonist should be considered in patients who are intolerant to an ACEIb in this situation, although long-term survival data are not available. Combination therapy with an ACEI and angiotensin II receptor antagonist may be considered in patients with diabetic kidney disease with persistent	

			proteinuria (> 1gm/day) or microalbuminuriad despite being appropriately titrated to an optimal dose of an ACEI (note: combination with an ACEI and nondihydropyridine calcium channel blocker may also be considered; if an angiotensin II receptor antagonist is prescribed in combination with an ACEI, the angiotensin II receptor antagonist should be discontinued if the patient does not respond, or experiences an adverse event such as hyperkalemia, as the long-term benefits and/or safety of this combination have not been established). III. Recommendations for Patients with HTN - Losartan As per national treatment guidelines, thiazide-type diuretics are the preferred agents for patients with uncomplicated HTN; other agents reported to have benefits in reducing morbidity or mortality should be considered in patients who have a contraindication to or are inadequately controlled [e.g., ACEI, beta-adrenergic blocker, or long-acting calcium channel blocker (CCB)]. These agents in turn can be used together or in combination with other selected agents to achieve goal blood pressure. An angiotensin II receptor antagonist may be used as adjunct treatment or as specified below (also refer to Discussion section). In addition, angiotensin II receptor antagonists are appropriate in patients who have a compelling indication for an ACEI, but are intolerant to an ACEI (refer to Discussion section). Criteria for Angiotensin II Receptor Antagonist: p In a patient treated with an ACEI in combination therapy with other antihypertensive agents (e.g., thiazide-type diuretics, beta-adrenergic blockers, long-acting CCBs, etc), where the blood pressure is at or near goal, but is intolerant to the ACEI** ---- * Systolic HF = LVEF < 40% and New York Heart Association (NYHA) functional class II-IV. ** Intolerant to an ACEI = Unable to tolerate an ACEI due to cough or other non life-threatening reason. It is unknown if an angiotensin II receptor antagonist can be safely used as an alternative in patients who develop renal dysfunction, hyperkalemia, or angioedema with an ACEI; or where treatment with an ACEI is limited due to renal dysfunction, as these adverse events have also occurred with the use of an angiotensin II receptor antagonist (refer to Discussion section). *** Type 2 DM and nephropathy refers to patients with nephropathy (proteinuria > 0.5g/24h or microalbuminuriad) due to type 2 DM. **** 24 hour urine albumin collection > 30 mg/24 hours (Confirmed with 2-3 consecutive urine

			samples within a 3 month period separated by at least 1-2 weeks) or Spot urine albumin/creatinine ratio > 30mg urine albumin/gram urine creatinine (Confirmed with 2-3 consecutive urine samples within a 3 month period separated by at least 1-2 weeks). April 2005 Equivalent daily doses for ARB conversion: candesartan losartan valsartan 4 mg 25 mg 80 mg (40 mg bid) 8 mg 25 mg 80 mg (40 mg bid) 16 mg 50 mg 160 mg (80 mg bid) 32 mg 100 mg 320 mg (160 mg bid) April 2005 Recommendation for ARB to use in patients with systolic heart failure requiring combination therapy: (1) For patients requiring the combination of an ACEI, ARB, and beta-blocker, candesartan is the preferred ARB; and (2) For patients requiring the combination of an ACEI and ARB but not taking a beta-blocker, valsartan is the preferred ARB. This recommendation is only to guide the the choice of ARB in these situations, and is not meant to (mis)lead providers into pursuing an ACEI -ARB combination therapy before starting a beta blocker. June 2005	
AN300	CAPECITABINE 500MG TAB	XELODA	Restrictions per local facility	NON-FORMULARY
DE650	CAPSAICIN 8% TOPICAL PATCH	QUTENZA	Non-Formulary: no criteria for use	NON-FORMULARY
AM054	CARBENICILLIN 382MG TAB	GEOCILLIN	Non-Formulary: no criteria for use	NON-FORMULARY
CN500	CARBIDOPA 25MG TAB	LODOSYN	Carbidopa (Lodosyn) is Non-Formulary, restricted to Neurology, Geriatrics, or local facility equivalent for patients who have failed or are intolerant to appropriate dosages of carbidopa/levodopa (Sinemet) therapy	NON-FORMULARY
CV100	CARVEDILOL EXTENDED RELEASE ORAL TAB	COREG CR	Non-Formulary: no criteria for use	NON-FORMULARY
GA209	CASANTHRANOL/DOCUSATE NA CAP (OTC)	PERICOLACE	Non-Formulary: no criteria for use	NON-FORMULARY
GA204	CASCARA SAGRADA ORAL FLUID EXTRACT (OTC)	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
GA209	CASCARA/MAGNESIUM HYDROXIDE CONC SUSP (OTC)	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AM700	CASPOFUNGIN INJ	CANCIDIS	Caspofungin (Cancidas) is non-formulary, restricted to approval by Infectious Disease, Marrow Transplant Program, Liver Transplant Program or local facility equivalent, for patients failing or who intolerant of amphotericin B; or other appropriate clinical situations in which patients are failing or are intolerant of first-line anti-fungal therapy.	NON-FORMULARY
AM119	CEFTAROLINE FOSAMIL	TEFLARO	NON-FORMULARY,CLINICAL RECOMMENDATIONS	NON-FORMULARY

AM102	CEFUROXIME NA INJ	ZINACEF	Restrictions per local facility	NON-FORMULARY
MS120	CELECOXIB ORAL CAPS	CELEBREX	COX-2 Inhibitor Criteria NOTE: Lack of response to non-selective NSAIDs is not a reason to use a COX-2 inhibitor. COX-2 inhibitors are not more effective than other NSAIDs. Dyspepsia is not a reason to use a COX-2 inhibitor since COX-2 inhibitors may also cause dyspepsia. Clinicians should give strong consideration for therapeutic modalities other than COX-2s or nonselective NSAIDs. Patients with cardiovascular or cerebrovascular disease: Until more conclusive evidence is obtained from prospective studies evaluating the cardiovascular safety of the COX-2 inhibitors, they should be avoided, if possible, in patients with a history of or sufficient risk for cardiovascular or cerebrovascular disease. Use of alternative modalities is strongly recommended, and COX-2 inhibitors should be discontinued, if possible. [January 2005] Approximate cost comparison (30 day supply): [note: these costs are not kept current - refer to local sources for actual prices] COX-2 Inhibitor Rofecoxib..... $45.00 Non-Formulary NSAIDs Tolmentin..... $40.00 Nabumetone.... $38.00 Formulary NSAIDs Ibuprofen $1.80 Indomethacin.. $2.70 Diclofenac.... $20.00 Naproxen..... $4.20 Sulindac..... $2.10 Piroxicam..... $2.70 Etodolac..... $10.00 Others Salsalate $2.70 Acetaminophen $2.28 Misoprostol (to be used w/ NSAID) $36.00 COX-2 Inhibitor Gastrointestinal Risk Assessment Tool (GI SCORE) TO BE COMPLETED BY PROVIDER 1. Patient Age Age Points Age Points Age Points 85 years 18 SCORE:_____ 2. Does the patient have rheumatoid arthritis (not osteoarthritis or other forms of arthritis)? No: 0 points Yes: 2 points SCORE:_____ 3. Is the patient taking prednisone or any other corticosteroid, and for how many months? Months Points 0 0 1-3 1 4-6 3 7-10 4 11-12 5 SCORE:_____ 4. Has the patient ever been hospitalized for a stomach or intestinal problem such as bleeding or an ulcer? (If the answer is yes, skip the next question.) No: 0 points Yes: 8 points SCORE:_____ 5. Ask the patient if he or she has ever had gastrointestinal side effects (heartburn, stomach pain, nausea, vomiting) when taking NSAID pain relievers? No: 0 points Yes: 2 points SCORE:_____ 6. Ask the patient to rate his or her current health status on the following scale: Health Status Points Very Poor 4 Poor 3 Fair 2 Well 1 Very Well 0 SCORE:_____ Total Score:_____ Evaluation of Patients Risk for	NON-FORMULARY

			Serious NSAID-Induced Gastrointestinal Event Within the Next Year: Risk Level Points Recommendations 1-No risk 0-10 Patients may use a non-selective formulary NSAID 2-Moderate risk 11-15 Patients may use a non-selective formulary NSAID 3-Significant risk 16-20 30 days use--salsalate or etodolac (and acetaminophen for OA); if failure or intolerant, then COX-2 inhibitor 4-Substantial risk >20 Use salsalate (and acetaminophen for OA). If failure or intolerant, then COX-2 inhibitor EXCLUSIONS: Patients should not be receiving any of the following: Concomitant anti-secretory therapy (i.e., PPI) Concomitant cytoprotective (i.e., misoprostol) therapy Concommitant aspirin therapy Patients with a GI score of 16 (significant/substantial risk) and requires chronic (> 30 days) of therapy, and a trial of salsalate (and acetaminophen for osteoarthritis) yielded either failure or intolerance.	
GA400	CERTOLIZUMAB 200 MG/ML INJ,SOLN	CIMZIA	Non-Formulary: no criteria for use	NON-FORMULARY
GA400	CERTOLIZUMAB PEGOL INJ	CIMZIA	Non-Formulary: no criteria for use	NON-FORMULARY
AN900	CETUXIMAB INJ	ERBITUX	Cetuximab is non-formulary, restricted to (1) use in combination with irinotecan for the treatment of metastatic colorectal cancers that express EGFR and are refractory to irinotecan-based therapy, or (2) use as monotherapy for the treatment of metastatic colorectal cancers that express EGFR in patients intolerant to irinotecan therapy. January 2005 VISN 20 P&T	NON-FORMULARY
OR500	CETYLPYRIDINIUM 0.05% MOUTHWASH (OTC)	CEPACOL	Non-Formulary: no criteria for use	NON-FORMULARY
AU300	CEVIMELINE ORAL	EVOXAC	Non-Formulary: no criteria for use	NON-FORMULARY
CV701	CHLOROTHIAZIDE INJ 25MG/ML 20ML	DIURIL	Non-Formulary: no criteria for use	NON-FORMULARY

CN701	CHLORPROMAZINE SUPP RTL	THORAZINE	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CN701	CHLORPROTHIXENE INJ	TARACTIN	Non-Formulary: no criteria for use	NON-FORMULARY
CN701	CHLORPROTHIXENE ORAL	TARACTIN	Non-Formulary: no criteria for use	NON-FORMULARY
RE101	CICLESONIDE SPRAY NASAL INHALATION	OMNARIS	Non-Formulary: no criteria for use	NON-FORMULARY
DE102	CICLOPIROX NAIL LACQUER TOP SOLN	PENLAC	Ciclopirox (Penlac) is non-formulary, restricted to non-cosmetic treatment of onychomycosis with approval by Infectious Diseases, Dermatology, or local facility equivalent for patients unable to take terbinafine or other oral agents.	NON-FORMULARY

CV900	CILOSTAZOL ORAL	PLETAL	VA National Criteria Checklist for Cilostazol (Pletal) - Non-Formulary Use Exclusion Criteria Patient with one of the following conditions: - Patient with congestive heart failure - Diagnosis of neurogenic claudication - Active bleeding disorder (i.e.; peptic ulcer) - Hypersensitivity to cilostazol - Severe liver failure (enzymes 3 times upper limit) If yes to any condition, patient is ineligible to receive cilostazol Inclusion Criteria (both must be met) - Patient with moderate to severe intermittent claudication - Patient is not a candidate for surgical or catheter based interventions Non Pharmacologic Management - exercise therapy program http: www.prevention.va.gov/January_2008.asp - smoking cessation program as outlined in the VA/DoD Clinical Practice Guidelines - weight reduction http://www.move.va.gov/ - control of diabetes, blood pressure, lipids as outlined in the VA/DoD Clinical Practice Guidelines It is strongly recommended that patients be evaluated and an attempt made at risk factor reduction prior to cilostazol initiation. Dosing - Patient receiving therapy with an inhibitor of the CYP3A4 system (i.e. erythromycin, ketoconazole, diltiazem, itraconazole:. Cilostazol dose is 50 mg orally, twice daily - Patient receiving therapy with an inhibitor of the CYP2C19 system (i.e. omeprazole): Cilostazol dose is 50 mg orally, twice daily - Patient on no interacting drug therapy: Cilostazol dose is 100 mg orally, twice daily. - Cilostazol dose should be taken 30 minutes before or 2 hours after a meal. Monitoring (Therapy should be discontinued if no improvement noted) - Patients should be reevaluated at 6months to document any symptomatic improvement SPECIAL CONSIDERATIONS Patients with a creatinine clearance	NON-FORMULARY

HS900	CINACALCET ORAL	SENSIPAR	Cinacalcet is non-formulary, restricted to Endocrinology and Nephrology Services or local facility equivalent for use in patients who meet a modification of the National Criteria for Non-Formulary Use of Cinacalcet, which can be found (in PDF format) at http://www.vapbm.org/criteria/Cinacalcet%20Criteria (web%2001-06-05).pdf Note: Because of the (in the URL, you have to copy the URL and paste into Internet Explorer to access the site. Just clicking doesn't work. VISN 20 elected to strengthen the national criteria for use by exchanging OR for AND in the second line of the following section: Intact plasma parathyroid hormone (iPTH) level > 400 pg/ml [or Bio-Intact (full-length) PTH > 200 pg/ml] in addition to A. AND B.: A. PTH level > 400 pg/ml despite maximal tolerated doses of all forms of phosphate binders and vitamin D B. Calcium x phosphorus product > 55mg2/dl2 1 despite dietary restriction of phosphate to < 1gm/d AND 2 trial of calcium based phosphate bindersb AND 3 then addition of or change to sevelamer As cinacalcet may lower serum calcium, adjustment of phosphate binders may be required (i.e., sevelamer should be reduced with a goal of discontinuation, if possible, and calcium based binders adjusted to control phosphorus as indicated) OR Total serum calcium (corrected for serum albumin)a > 10.2mg/dl (or maximum per lab/facility) in a patient with parathyroid carcinoma despite standard therapy to control hypercalcemia January 2005, May 2005 VISN 20 P&T	NON-FORMULARY
OT109	CIPROFLOXACIN OTIC SOLUTION	CIPRODEX	Non-Formulary: no criteria for use	NON-FORMULARY
GA900	CISAPRIDE ORAL	PROPULSID	Non-Formulary: no criteria for use	NON-FORMULARY
CV900	CITRATE PHOSPHATE DEXTROSE INJ 5000ML	N/A	Non-Formulary: no criteria for use	NON-FORMULARY

IR100	CITRIC ACID/GLUCONIC ACID	N/A	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CN200	CLEVIDIPINE INJ,EMULSION	CLEVIPREX	Non-Formulary: no criteria for use	NON-FORMULARY
CN302	CLORAZEPATE 7.5MG TAB	TRANXENE	Non-Formulary: no criteria for use	NON-FORMULARY
XA108	CLOTH TAPE, MEDIPORE	MEDIPORE 3M CLOTH TAPE	Non-Formulary: no criteria for use	NON-FORMULARY
GU300	CLOTRIMAZOLE VAG TAB (OTC)	MYCELEX	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
BL117	COAGULATION FACTOR VIIA, HUMAN RECOMBINANT	NOVOSEVEN	The VA National Recommendations Concerning the Off-Label Use of the Non-Formulary Recombinant Activated Human Coagulation Factor VII (rFVIIa) can be found at http://vaww.pbm.va.gov/criteria/novoseven.pdf . Adopted by VISN 20 April 2007	NON-FORMULARY
DE802	COAL TAR 5% TOP GEL (OTC)	ESTAR	Non-Formulary: no criteria for use	NON-FORMULARY
CN101	CODEINE PHOSPHATE INJ 60MG/ML	CODEINE	Non-Formulary: no criteria for use	NON-FORMULARY
MS900	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	XIAFLEX	NON-FORMULARY, CFU	NON-FORMULARY

OP109	CONIVAPTAN INJ	VAPRISOL	Non-Formulary: no criteria for use	NON-FORMULARY
HS900	CONTRACEPTIVE FOAM,NONOXYNOL-9 12.5%	VCF VAG CONTROL	Non-Formulary: no criteria for use	NON-FORMULARY
OT109	CRESYL ACETATE OTIC SOLUTION	CRESYLATE	Restricted to ENT for office use only. June 2005 VISN 20 P&T; Removed from VISN 20 Formulary May 2007	NON-FORMULARY
RE109	CROMOLYN SODIUM AEROSOL, ORAL	N/A	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
GU900	CROSS-LINKED BOVINE-DERIVED COLLAGEN INJ	CONTIGEN		NON-FORMULARY
VT101	CYANOCOBALAMIN NASAL	NASCOBAL	Non-Formulary: no criteria for use	NON-FORMULARY
HS501	CYCLOBENZAPRINE CAP,SA	AMRIX	Non-Formulary: no criteria for use	NON-FORMULARY
MS900	DALFAMPRIDINE	ACCORDA	NON-FORMULARY, CFU	NON-FORMULARY
BL100	DANAPAROID NA 750 UNITS/0.6ML INJ	ORGARAN	Lepirudin (Refludan) is formulary, restricted to patients with HIT who require anticoagulation. Danaparoid (Orgaran) and argatroban (Acova) are non-formulary. Sept 2006 VISN 20 P&T Any of these agents can be ordered on a non-formulary basis with appropriate justification. The specific agent to use should be determined by the prescriber based on the individual patient. July 2001	NON-FORMULARY
AM900	DASATANIB ORAL TAB	SPRYCEL	Non-Formulary: no criteria for use	NON-FORMULARY
AN300	DECITABINE INJ	DECOGEN	Non-Formulary: no criteria for use	NON-FORMULARY
AN500	DEGARELIX	FERRING	NON-FORMULARY	NON-FORMULARY
HS200	DEMULEN 1/35 TAB 28 DAY PACK	DEMULEN	Non-Formulary: no criteria for use	NON-FORMULARY
HS200	DEMULEN 1/50 TAB 28 DAY PACK	DEMULEN	Non-Formulary: no criteria for use	NON-FORMULARY
IM900	DENOSUMAB	XGEVA	NON-FORMULARY	NON-FORMULARY

DE900	DESOXYRIBONUCLEASE/FIBRINOLYSIN TOP OINT	ELASE	Non-Formulary: no criteria for use	NON-FORMULARY
CN609	DESVENLAFAXINE	PRISTIQ	NON-FORMULARY	NON-FORMULARY
OP350	DEXAMETHASONE 0.1%/NEO/POLYMX OPH SUSP	MAXITROL	Non-Formulary: no criteria for use	NON-FORMULARY
	DEXAMETHAZONE INTRAVITREAL IMPLANT	OZURDEX	NON-FORMULARY	NON-FORMULARY
GA900	DEXLANSOPRAZOLE DDR	DEXILANT	NON-FORMULARY	NON-FORMULARY
RE302	DEXTROMETHORPHAN T.R. SUSP 30M	DELSYM	Non-Formulary: no criteria for use	NON-FORMULARY
CN302	DIAZEPAM RECTAL GEL	DIASTAT	Diazepam rectal gel is non-formulary, restricted to a neurologist or local facility equivalent for outpatients with unstable refractory seizures who are at home or residing in a nursing home with a caregiver.	NON-FORMULARY
MS102	DICLOFENAC EPOLAMINE TOPICAL PATCH	FLECTOR	Non-Formulary: no criteria for use	NON-FORMULARY
MS900	DICLOFENAC/MISOPROSTOL ORAL TAB	ARTHROTEC	Diclofenac/misoprostol (Arthrotec) is non-formulary, available on a non-formulary basis for selected patients for whom this combination of drugs is likely to be uniquely beneficial.	NON-FORMULARY
HS300	DIETHYLSTILBESTROL 1MG TAB	STILPHOSTROL	Non-Formulary: no criteria for use	NON-FORMULARY
CN105	DIHYDROERGOTAMINE NASAL SPRAY	MIGRANAL	Dihydroergotamine (DHE) nasal spray is non-formulary, restricted to failure of first line medication(s) for migraine (NSAIDs, ergotamine, or injectable dihydroergotamine). May 2007	NON-FORMULARY
CN400	DIVALPROEX NA 250MG, 500MG EC TAB	DEPAKOTE EC DELAYED RELEASE	Divalproex sodium SA (Depakote ER) is the only available divalproex sodium product on the VISN 20 Formulary. March 2006 VISN 20 P&T Committee	NON-FORMULARY
CV300	DOFETILIDE ORAL	TIKOSYN	Use VA dispensing guidelines and protocols.	NON-FORMULARY
	DONEPEZIL	ARICEPT	NON-FORMULARY	NON-FORMULARY
AM119	DORIPENEM INJ,LYPHL	DORIBAX	Restricted to Infectious Disease Service or local facility equivalent.	NON-FORMULARY
VT509	DOXERCALCIFEROL INJ	HECTORAL	Doxercalciferol (Hectorol) is non-formulary, restricted to renal dialysis patients failing calcitriol therapy or intolerant to calcitriol. Acceptable evidence for failure to calcitriol would be inability to reach the therapeutic end points of therapy at maximum calcitriol dose or onset of severe adverse effects such as hyperphosphatemia or hypercalcemia. The oral form of doxercalciferol should be used for patients who can take oral medication, otherwise doxercalciferol injection may be used.	NON-FORMULARY

VT509	DOXERCALCIFEROL ORAL	HECTORAL	Doxercalciferol (Hectorol) is non-formulary, restricted to renal dialysis patients failing calcitriol therapy or intolerant to calcitriol. Acceptable evidence for failure to calcitriol would be inability to reach the therapeutic end points of therapy at maximum calcitriol dose or onset of severe adverse effects such as hyperphosphatemia or hypercalcemia. The oral form of doxercalciferol should be used for patients who can take oral medication, otherwise doxercalciferol injection may be used.	NON-FORMULARY
XA199	DRESSING, EXU-DRY	EXU-DRY WOUND DRESSING	Non-Formulary: no criteria for use	NON-FORMULARY
CV300	DRONEDARONE	MULTAQ	NON-FORMULARY, CFU	NON-FORMULARY
CV300	DRONEDARONE		NON-FORMULARY, CFU	NON-FORMULARY
CV300	DRONEDARONE 400MG TAB	MULTAQ	Non-Formulary: no criteria for use	NON-FORMULARY
CV300	DRONEDARONE ORAL TAB	MULTAQ	Non-Formulary: no criteria for use	NON-FORMULARY
BL900	DROTRECOGIN ALPHA INJ	XIGRIS	Drotrecogin alfa [activated] (Xigris) Criteria for Non-Formulary Use January 2002 (Updated June 2005, June 2009) VHA Pharmacy Benefits Management Services and Medical Advisory Panel These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high-quality, cost-effective drug therapy. These criteria are not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations. Because of the potentially serious toxicity, lack of information for the wide spread use in high risk patients and the marginal efficacy demonstrated in some of the groups in the clinical trials, VA clinicians should consider use of drotrecogin alfa (activated) only after the approval of a pulmonary, critical care, or infectious disease attending physician or other designee determined locally (e.g., critical care fellow). The following recommendations are provided for the use of drotrecogin alfa (activated) in VHA. EXCLUSION CRITERIA (If one is selected, patient is NOT eligible) Contraindications 0 Active internal bleeding 0 Recent (within 3 months) hemorrhagic stroke 0 Recent (within 2 months) intracranial or intraspinal surgery, or severe head trauma requiring hospitalization 0 Trauma with an increased risk of life-threatening bleeding 0 Presence of an epidural catheter 0 Intracranial neoplasm or mass lesion or evidence of	NON-FORMULARY

			cerebral herniation 0 Known hypersensitivity to drotrecogin alfa (activated) or any component of the product 0 Life expectancy < 1 month or decision not to pursue aggressive medical care Bleeding-related warnings which led to exclusion from the phase III trial. Mortality and serious bleeding event rates were higher in patients with one of the following baseline bleeding-related warnings in a subsequent retrospective study. 0 Concurrent therapeutic heparin at doses to treat an active thrombotic or embolic event 0 Platelet count 3.0, even if the INR is reversed (with fresh frozen plasma or vitamin K) 0 Recent (within 6 weeks) gastrointestinal bleeding (unless corrective surgery had been performed) 0 Recent administration (within 3 days) of thrombolytic therapy (except for treatment of thrombosed catheters) 0 Recent administration (within 7 days) of aspirin (>650 mg/day) or other platelet inhibitors 0 Recent administration (within 7 days) of glycoprotein IIb/IIIa inhibitors 0 Recent administration (within 12 hours) of greater than 10,000 U of antithrombin III 0 Recent (within 3 months) ischemic stroke 0 Intracranial arterio-venous malformation or aneurysm 0 Known bleeding diathesis 0 Chronic severe hepatic disease (portal hypertension, cirrhosis, chronic jaundice or ascites) Inclusion Criteria Suspected or proven infection (One of the following must be present for patient to be eligible) Patient has known or suspected infection defined as: 0 Positive culture (indicating infection rather than colonization or contamination) 0 Abnormal number of neutrophils in a normally sterile body fluid 0 Perforated viscus 0 Radiological and clinical evidence of pneumonia Other syndrome with high probability of infection (e.g., ascending cholangitis) Monitoring (The following must be selected for patient to be eligible) 0 Patient is receiving continuous monitoring in the intensive care unit SIRS (At least 3 of the 4 following criteria must be present for patient to be eligible) Patient has three or more signs of systemic inflammatory response syndrome (SIRS) as defined as: 0 Core temp of >/= 100.4 F (38C) or /= 90 beats/minute 0 RR >/= 20 breaths/min or PaCO2 = 32 mmHg or mechanical ventilation for acute (not chronic) respiratory process 0 WBC >/= 12,000/mm3 or /= 10% immature neutrophils Organ system dysfunction (At least 2 of the following must be present for patient to be eligible) Patient has dysfunction of 2 or more organs or systems defined as: 0 CARDIOVASCULAR: Arterial systolic BP /= 90 mm	

			HG or MAP >/= 70 mm Hg 0 RENAL: Urine output < 0.5 ml/kg/hr for > 1 hour, despite adequate fluid resuscitation 0 RESPIRATORY: PaO2/FiO2 < 80,000/mm3 or decreased by 50% from highest value in the previous 72 hours 0 METABOLIC: PH /= 5 mEq/L with plasma lactate > 1.5 times the upper limit of normal APACHE II Score (must be selected for patient to be eligible) Acute Physiology and Chronic Health Evaluation (APACHE) II Score: 0 APACHE II >/= 25 and < 53 as calculated on basis of physiologic and laboratory data obtained within the immediately preceding 24 hour period (http://www.sfar.org/scores2/apache22.html). No benefit of drotrecogin alfa has been demonstrated in patients with severe sepsis and low risk of death (e.g., APACHE score < 18 years or weight > 135 kg (298 pounds) 0 Patients who are pregnant or breastfeeding 0 Surgery requiring general or spinal anesthesia within the preceding 12 hours, active post-operative bleeding, intra-cranial surgery within 3 months, or anticipated surgery requiring general or spinal anesthesia during the infusion 0 Hypercoagulable condition 0 Highly suspected deep venous thrombosis or pulmonary embolism 0 Acute pancreatitis with no established source of infection 0 HIV+ with < 50 CD4+ cells or status-post bone marrow, lung, liver, pancreas or small bowel transplant 0 Chronic renal failure requiring hemodialysis or peritoneal dialysis (acute renal failure was not an exclusion) Recent (within 3 months) documented or highly suspected DVT or pulmonary embolism Patient meets all inclusion criteria and does not have any exclusion criteria 0 Yes 0 No July 2009 VISN 20 P&T	

CN609	DULOXETINE ORAL CAP	CYMBALTA	National Criteria for Non-Formulary Use of Duloxetine in Painful Diabetic Neuropathy VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel Exclusion Criteria: If the patient has ANY item below, then the patient should NOT receive duloxetine. 1. Patient has end-stage renal impairment (requiring dialysis). 2. Patient has severe renal impairment (estimated CrCl < 30 ml/min). 3. Patient has hepatic impairment or chronic liver disease. 4. Patient has substantial alcohol intake. 5. Patient has uncontrolled narrow-angle glaucoma or uncontrolled hypertension. 6. Patient is taking thioridazine or monoamine oxidase inhibitors. Inclusion Criteria: Patient must have both in order to meet criteria. 1. Patient has painful diabetic neuropathy. 2. Patient has well documented insufficient response despite an adequate trial (duration of 6-12 weeks at doses shown below) of at least one oral agent, used alone or in combination, from 2 of the following 4 drug classes (minimum of 2 oral agents, total) OR patient has documented intolerance, hypersensitivity, or contraindication to the following agents and is therefore precluded from undertaking an adequate trial of at least one oral agent from 2 of the 4 drug classes. Drug Classes for Painful Diabetic Neuropathy: 1. Antidepressants, tricyclic: e.g., amitriptyline (nortriptyline) 25-150 mg/d; desipramine 12.5-200 mg/d; imipramine 25-225 mg/d 2. Antidepressants, SNRI: e.g., venlafaxine 150-225 mg/d 3. Antiepileptic drugs: e.g., carbamazepine 200-600 mg/d, gabapentin 300-3600 mg/d, phenytoin 300 mg/d, valproate 500-1200 mg/d 4. Opioid: e.g., tramadol 50-400 mg/d The criteria suggest tramadol, a nonscheduled opioid, as a prior treatment alternative to duloxetine. The criteria do not recommend a prior trial of schedule II to IV opioids before considering duloxetine. However, patients already prescribed schedule II to IV opioids may be considered for duloxetine therapy as long as the minimum of 2 prior agents is met. VISN 20 P&T Committee 1-16-09 .	NON-FORMULARY
DE700	DYCLONINE 1% SOLN 30M	DYCLONE	Non-Formulary: no criteria for use	NON-FORMULARY
BL500	ECULIZUMAB 10MG/ML INJ,SOLN	SOLIRIS	VA Non-Formulary Criteria for Use Eculizumab (Soliris) FDA APPROVED INDICATION FOR USE Eculizumab is indicated for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. EXCLUSION CRITERIA (If one is selected, patient is	NON-FORMULARY

			NOT eligible) 0 Unresolved bacterial infections - especially Neisseria meningitidis or other encapsulated organisms. 0 Patients with known complement deficiency. 0 Patients with any (even remote) history of meningococcal infections. 0 Patients with a prior history of bone marrow transplantation. INCLUSION CRITERIA To be eligible, all of the following criteria must be met: 0 PNH type III of 10% or more in 1 or 2 cell lines (erythrocytes or granulocytes). 0 Serum lactate dehydrogenase levels at least 1.5 times the upper limit of normal. 0 One of the following conditions: * Symptoms of PNH that inhibit the patient???s quality of life. * Transfusion dependence (defined by at least 4 transfusions in the previous 12 months). * Thrombotic event(s) attributable to paroxysmal nocturnal hemoglobinuria. 0 Patient received vaccination for meningococcal, pneumococcal polysaccharide and Haemophilus influenzae type b at least two weeks prior to first dose of eculizumab. If patient has been previously vaccinated for these agents, consider revaccination according to CDC guidelines (www.cdc.gov). 0 Patient was counseled regarding risks versus benefits of eculizumab therapy particularly the risk of meningococcal infection and provided with a patient safety card. 0 For women of child-bearing potential, a pregnancy test should be performed prior to receiving the vaccines and eculizumab. DOSAGE AND ADMINISTRATION (Refer to PI for dosage recommendations in organ dysfunction) 600 mg via 35 minute intravenous infusion every 7 days for 4 weeks, followed by 900 mg 7 days after the fourth dose, and maintained at 900 mg every 14 days thereafter. RECOMMENDED MONITORING 0 Signs and symptoms of infection: Patients have increased risk in developing infections caused by encapsulated bacteria (e.g., Neisseria meningitidis, Streptococcus pneumoniae, Haemophilus influenzae) particularly serious meningococcal infections such as septicemia and/or meningitis. Even patients vaccinated against meningococcus are at risk for meningococcal infections. 0 Infusion-related reactions including anaphylaxis or other hypersensitivity reactions. 0 Serum LDH levels to monitor response to therapy. ISSUES FOR CONSIDERATION 0 Meningococcal vaccine: Consideration for revaccination should occur if patient received polysaccharide meningococcal vaccine more than 3 years ago or if previously received meningococcal protein conjugate vaccine more than 5	

			years ago. Quadravalent, conjugated meningococcal vaccines are recommended. 0 Eculizumab and vaccinations (meningococcal, Hib, and pneumococcal) are pregnancy category C. 0 If eculizumab therapy is discontinued, patient should be closely monitored for hemolysis and other potential reactions for at least 8 weeks. September 2008 VISN 20 P&T Committee	
DE810	EFALIZUMAB INJ	RAPTIVA	Alefacept, Etanercept, Efalizumab and Infliximab Non-Formulary Criteria for Psoriasis Use Alefacept, etanercept, efalizumab and infliximab are non-formulary for the treatment of severe psoriasis or psoriatic arthritis, restricted to physicians experienced in treating these indications such as Rheumatology, Dermatology, or local facility equivalent. Patients must meet all of the following criteria: 1. Patient is an adult > 18 years of age who has chronic (> 6 months) severe plaque psoriasis (for using any biologics) or psoriatic arthritis (for etanercept). Criteria for severe psoriasis: all four of the following: a. Disease is disabling or impairs the patient???s quality of life (self-reported), including the ability to work and activities of daily living AND b. Disease does not have a satisfactory response to treatments that have minimal risks AND c. The patient is willing to accept life-altering adverse effects to achieve less disease or no disease AND d. More than 10% of body surface is involved or other factors apply (patient???s attitude about disease; location of disease [e.g., face, hands, fingernails, feet, genitals]; symptoms [e.g., pain, tightness, bleeding, or severe itching]; arthralgias or arthritis). 2. Patient is a candidate for systemic antipsoriatic therapy or ultraviolet therapy, and has documented inaccessibility to ultraviolet therapy OR documented inadequate response, contraindication, intolerance, or hypersensitivity to methotrexate and, if available, ultraviolet therapy (PUVA or UVB) with or without oral retinoids (e.g., acitretin). 3. Patient has no contraindications to biologic therapy or other condition that would preclude the use of biologic agents. 4. No concurrent live or live-attenuated vaccines during therapy. 5. No concurrent immunosuppressive therapy except those used in the treatment of psoriasis. Ultraviolet therapy with or without retinoids is considered by experts to be safe to use with biologic agents, although published reports of such combination therapy are lacking at this time. Methotrexate is approved for concurrent use with etanercept and infliximab. Justification for any	NON-FORMULARY

			concurrent use of systemic or other immunosuppressive antipsoriatic therapy with biologic agents (such as for transitioning or potential additive effects in partial responders) should be clearly[Wed Nov 10 16:18:03 2010] dofile.pl: Wide character in print at c:\inetpub\wwwroot\reports\dofile.pl line 96. documented. Current prescribing information for the biologics advises against such combinations. Therefore, clinicians should weigh the potential risks and benefits before deciding to use concurrent ultraviolet, systemic, or other immunosuppressive therapy with biologics. VISN 20 P&T Committee November 19, 2004	
DE900	EFLORNITHINE HYDROCHLORIDE	VANIQA	Non-Formulary: no criteria for use	NON-FORMULARY
HS200	EMERGENCY CONTRACEPTION KIT (CONTENTS IN MINUTES)	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
CV500	ENALAPRIL-FELODIPINE ORAL	LEXXEL	Non-Formulary: no criteria for use	NON-FORMULARY
OP103	EPINEPHRINE HCL 1% OPHTH SOLN	EPIFRIN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

OP103	EPINEPHRINE HCL 2% OPHTH SOLN	EPIFRIN		NON-FORMULARY
			FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	
CV704	EPLERENONE ORAL	INSPRA	Eplerenone is non-formulary, restricted to the following criteria: (1) For essential hypertension, highly restricted to only those patients who require treatment with an aldosterone blocker and cannot tolerate spironolactone due to endocrine-related adverse events; (2) For treatment of post-MI CHF, reserved for patients who are maximally treated with all other medications known to affect the outcome of CHF (ACEIs, ARBs, Beta-blockers, diuretics) and are unable to tolerate spironolactone due to documented endocrine adverse events; and (3) eplerenone may be considered as an alternative for a patient who develops adverse events on spironolactone, who has a hyperaldosterone state such as primary hyperaldosteronism or liver disease syndromes, and has intolerance to amiloride with or without a diuretic. January 2005 VISN 20 P&T	NON-FORMULARY
CN105	ERGOTAMINE TARTRATE SL ORAL	ERGOSTAT	Non-Formulary: no criteria for use	NON-FORMULARY

AM900	ERLOTINIB ORAL	TARCEVA	National VA Non-Formulary Criteria for Use of Erlotinib (Tarceva) #1 Diagnosis Patient with locally advanced or metastatic non-small cell lung cancer after progression on at least one prior chemotherapy treatment An option for first-line therapy in patients with bronchioloalveolar carcinoma (BAC) after review on a case by case basis There is not adequate clinical data on use as first-line therapy, other than in patients with BAC, therefore it cannot be recommended at this time. If Yes, go to #2. If No, patient is not eligible for erlotinib Note: First-line use in combination with chemotherapy did not show a survival advantage ------- #2 Exclusion Criteria Patient with any one of the following conditions: ECOG Performance Status http://www.ecog.org/general/perf_stat.html No prior chemotherapy for advanced disease1(except BAC) Known central nervous system metastases who are symptomatic or not on a stable dose of corticosteroids for at least 4 weeks prior to start of therapy Significant history of cardiac disease: uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, ventricular dysrhythmia requiring medication Women of child-bearing potential not using adequate contraception Women actively breastfeeding. Clinically significant ophthalmologic or gastrointestinal abnormalities affecting the epithelium: severe dry eye syndrome, keratoconjunctivitis sicca, Sjogren???s syndrome, severe exposure keratopathy, uncontrolled Crohn???s disease or ulcerative colitis If No to all conditions, patient is eligible for erlotinib. ------- #3 Discontinuation Unacceptable Toxicity Suspicion of Interstitial Lung Disease- new or progressive dyspnea, cough, and fever Progressive Disease- at least a 20% increase in the sum of the largest diameter of measurable lesions from baseline or the appearance of new lesions* *There is no evidence of benefit of treating once the disease begins to progress ---------- #4 Monitoring Routinely monitor AST/ALT and bilirubin Pulmonary symptoms such as dyspnea, cough and fever Chest film or CT scan after 1 month, then every 2 months Potential drug interactions with CYP3A4 inhibitors, inducers and warfarin (or other Coumadin-derived anticoagulants) Severity of diarrhea (May require loperamide) Complaints of eye irritation Dermatologic reactions October 21, 2005	NON-FORMULARY

CN609	ESCITALOPRAM	LEXAPRO	Non-Formulary: no criteria for use	NON-FORMULARY
HS300	ESTRADIOL VAGINAL RING	ESTRING	Restricted to Women's Health providers or local facility equivalent.	NON-FORMULARY
HS900	ESTROGENS 0.625/METHYLTESTOSTERONE 1.25MG TAB	ESTRATEST H.S.	Non-Formulary: no criteria for use	NON-FORMULARY
HS900	ESTROGENS 1.25/METHYLTESTOSTERONE 2.5MG TAB	ESTRATEST	Non-Formulary: no criteria for use	NON-FORMULARY
CN309	ESZOPICLONE ORAL TAB	LUNESTA	VISN 20 and VA National Eszopiclone Non-Formulary Criteria for Use Exclusion Criteria Patient with symptoms of insomnia associated with one or more of the following conditions: * 1. A psychiatric and/or medical illness without any, or an inadequate trial, of other formulary alternatives or nonpharmacological interventions deemed appropriate to use (e.g., sedating antidepressants, benzodiazepines). 2. Pregnancy 3. Active alcohol/illicit drug use/abuse/dependence 4. Concurrent use with any other sedative hypnotics or other medications including over-the counter analgesics that contain caffeine or herbal supplements (e.g., melatonin, St. John's Wort) for the treatment of symptoms related to insomnia. 5. No attempts or consideration has been made and documented to discontinue or adjust any medications/ substances known to affect sleep. *Part of the evaluation of insomnia should include assessment of other drugs or conditions (e.g., chemical dependence, sleep apnea) that may be interfering with sleep. Inclusion Criteria for Short-TermTherapy for Insomnia: 1. Patient with acute (short-term) insomnia defined as periods of sleep difficulty lasting less than one month and basic sleep interventions (e.g., sleep hygiene, relaxation training) have failed to improve sleep difficulties 2. Patient with acute (short-term) insomnia until treatment associated with any underlying psychiatric and/or medical illnesses takes affect (e.g., depression) 3. Intolerance/contraindication/documented failure to other appropriate formulary treatment alternatives (e.g., sedating antidepressants, benzodiazepines) Criterion 1 AND at least one of the two remaining criteria needs to be met for patient to be eligible to receive eszopiclone for the short-term management of insomnia. Please note: Hypnotics should generally be limited to 7-10 days of use for short-term therapy. The failure of symptoms of insomnia to improve after 7- 10 days of treatment may indicate the presence of an underlying condition that needs to be evaluated. Please note:	NON-FORMULARY

			Published trials of eszopiclone primarily in the elderly population (>65 years of age) have not been conducted longer than 2 consecutive weeks. Patient Resources for Basic Hygiene Education http://www.womenshealth.gov/faq/insomnia.htm#5 or http://www.aasmnet.org/FactSheet.aspx or http://www.sleepfoundation.org/ Example of a sleep diary: http://www.nhlbi.nih.gov/health/prof/sleep/insom_pc.pdf Professional Education: http://www.sleepfoundation.org/ or http://www.ahrq.gov/clinic/epcsums/insomnsum.htm Inclusion Criteria for Long-Term Therapy for Insomnia 1. Patient with DSM-IV criteria for chronic primary insomnia (? 6.5 hours of sleep/night and requires > 30 min to fall asleep each night for at least 1 month) AND basic sleep interventions (e.g., sleep hygiene, relaxation training) have failed to improve sleep difficulties and treatment such as cognitive behavioral therapy (e.g., stimulus control, sleep restriction, cognitive therapy, and sleep education), IF AVAILABLE and FEASIBLE, has not been successful. 2. Intolerance/ contraindication/documented failure to other appropriate formulary treatment alternatives (e.g., sedating antidepressants and benzodiazepines) For patients requiring long-term therapy, evaluation by a sleep specialist (e.g., neurologists, pulmonologists, psychiatrists, medical practitioners board certified in sleep medicine) or a behavioral therapist that are experienced in sleep intervention techniques is recommended. Both criteria need to be met for a patient to be eligible to receive eszopiclone for long-term management of insomnia. Please note: Published trials of eszopiclone primarily in the elderly population (>65 years of age) have not been conducted longer than 2 consecutive weeks. It is strongly recommended that patients be evaluated within 3-5 weeks of the initial Rx to document any improvement in the symptoms related to insomnia. Patients should be re-evaluated regularly and adjunctive behavioral modification therapy be continued. If not done, reconsideration should be made whether Rx for eszopiclone should be continued. Criteria dated February 2006 Adopted by VISN 20 April, 2006	
MS109	ETANERCEPT INJ 25MG VIAL	ENBREL	National PBM Drug Criteria for Use: ETANERCEPT (ENBREL)	NON-FORMULARY

			VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel Consider ETANERCEPT As MONOTHERAPY if: - Documented contraindications, intolerance (toxicity) and/or suboptimal response to an adequate trial of MTX; AND - Documented contraindications, intolerance and/or suboptimal response to > 1 standard DMARDS at standard target dose (unless significant toxicity limited the dose tolerated), regardless of whether they were prescribed sequentially or in combination: oral/injectable gold, hydroxychloroquine, sulfasalazine, penicillamine, azathioprine, leflunomide As COMBINATION THERAPY with MTX if: - Documented suboptimal response with full or maximally tolerated doses of MTX CRITERIA FOR ELIGIBILITY*: * Each patient's risk versus benefit should be carefully considered before initiating therapy (or continuing therapy) in instances where safety and efficacy have not been established (See Table 4). Choice of therapy should be based on physician discretion and clinical judgment. 1. Diagnosis of RA as defined by the American College of Rheumatology (ACR); AND 2. Active RA despite full and adequate treatment with > 1 standard DMARDs at standard or maximally tolerated dose; AND 3. Baseline monitoring parameters within normal limits (See Table 5). CRITERIA FOR EXCLUSION: 1. MTX naïve - If a patient has failed to demonstrate an	

			adequate response to a single DMARD other than MTX, MTX should be initiated with doses up to 25 mg/week (as tolerated) for at least 3 months, with or without other DMARDs; OR 2. If a patient has previously achieved remission on a given DMARD, he or she should be restarted on this previously effective DMARD prior to use of etanercept;OR 3. Contraindications to etanercept. (See Table 3). CRITERIA FOR CONTINUATION: After initiation of an agent, adequate response with decreased disease activity such as improvement in severity of affected joints or resolution of flares/decrease in flares within 8-12 weeks based on clinical judgment and quantitative measurements, including: 1. Improvement in validated quantitative measures of response such as the Health Assessment Questionnaire (HAQ), visual analog scales (VAS), Likert scales, joint tenderness and/or swelling, and laboratory data (ESR, CRP); AND 2. Improvement in the DAS score > 1.2; OR 3. Achievement of a DAS28 score of < 3.2; OR 4. > 20% improvement according to ACR 20% response criteria 5. Monitoring parameters at follow-up MUST be within normal limits (See Table 5). CRITERIA FOR WITHDRAWAL OF THERAPY: 1. Inefficacy - Inadequate response (despite confirmed compliance) within 8-12 weeks after starting treatment at the recommended dosing schedule (See Table 2); OR 2. Loss of efficacy/unacceptable disease activity - Ongoing disease activity after 3 consecutive months of maximum therapy despite confirmed compliance (i.e., Repetitive flares;

			progressive joint damage);OR 3. Development of drug-related toxicity or adverse events (See Tables 6 and 7). VISN 20 P&T Committee February 2009 . Alefacept, Etanercept, Efalizumab and Infliximab Non-Formulary Criteria for Psoriasis Use Alefacept, etanercept, efalizumab and infliximab are non-formulary for the treatment of severe psoriasis or psoriatic arthritis, restricted to physicians experienced in treating these indications such as Rheumatology, Dermatology, or local facility equivalent. Patients must meet all of the following criteria: 1. Patient is an adult > 18 years of age who has chronic (> 6 months) severe plaque psoriasis (for using any biologics) or psoriatic arthritis (for etanercept). Criteria for severe psoriasis: all four of the following: a. Disease is disabling or impairs the patient's quality of life (self-reported), including the ability to work and activities of daily living AND b. Disease does not have a satisfactory response to treatments that have minimal risks AND c. The patient is willing to accept life-altering adverse effects to achieve less disease or no disease AND d. More than 10% of body surface is involved or other factors apply (patient's attitude about disease; location of disease [e.g., face, hands, fingernails, feet, genitals]; symptoms [e.g., pain, tightness, bleeding, or severe itching]; arthralgias or arthritis). 2. Patient is a candidate for systemic antipsoriatic therapy or ultraviolet therapy, and has documented inaccessibility to ultraviolet therapy OR documented inadequate response, contraindication, intolerance, or hypersensitivity to methotrexate and, if available, ultraviolet therapy (PUVA or UVB) with or without oral retinoids (e.g., acitretin).	

			3. Patient has no contraindications to biologic therapy or other condition that would preclude the use of biologic agents. 4. No concurrent live or live-attenuated vaccines during therapy. 5. No concurrent immunosuppressive therapy except those used in the treatment of psoriasis. Ultraviolet therapy with or without retinoids is considered by experts to be safe to use with biologic agents, although published reports of such combination therapy are lacking at this time. Methotrexate is approved for concurrent use with etanercept and infliximab. Justification for any concurrent use of systemic or other immunosuppressive antipsoriatic therapy with biologic agents (such as for transitioning or potential additive effects in partial responders) should be clearly documented. Current prescribing information for the biologics advises against such combinations. Therefore, clinicians should weigh the potential risks and benefits before deciding to use concurrent ultraviolet, systemic, or other immunosuppressive therapy with biologics. November 19, 2004 VISN 20 P&T Committee	
HS200	ETHINYL ESTRADIOL 0.05MG /NORGESTREL 0.5MG TAB	OVRAL	Non-Formulary: no criteria for use	NON-FORMULARY
HS200	ETHINYL ESTRADIOL 30/NORGESTREL 0.3 TAB	LO-OVRAL	Non-Formulary: no criteria for use	NON-FORMULARY
HS200	ETHINYLESTRADIOL 0.03MG, NORETHINDRONE ACETATE 1.5MG	LOESTRIN FE 1/20 28 DAY PACK	Non-Formulary: no criteria for use	NON-FORMULARY
DE801	ETRETINATE ORAL	TEGISON	Non-Formulary: no criteria for use	NON-FORMULARY
CN100	EVENING PRIMROSE OIL	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AN900	EVEROLIMUS	AFINITOR	NON-FORMULARY	NON-FORMULARY
AN000	EVEROLIMUS	ZORTRESS	NON-FORMULARY	NON-FORMULARY
AN900	EXEMESTANE ORAL TAB	AROMASIN	Exemestane is restricted to the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy. Sept 2007 VISN 20 P&T	NON-FORMULARY
HS500	EXENATIDE INJ	BYETTA	National VA Criteria for Non-Formulary Use of Exenatide (Byetta) Exclusion criteria: Type 1 diabetes	NON-FORMULARY

			Patient requires insulin therapy Patient has end-stage renal disease or CrCl < 30ml/min Patient has severe gastrointestinal disease, including gastroparesis Patient has a history of pancreatitis* * There have been post-marketing reports of pancreatitis, including hemorrhagic or necrotizing pancreatitis and death in patients taking exenatide. The majority of patients had at least one other risk factor for acute pancreatitis. Relative exclusions to use of exenatide include triglyceride level > 500mg/dL, known gallstones with intact gallbladder, and alcohol abuse. Inclusion Criteria: The following 3 criteria must be met: 1. The provider specializes in diabetes management 2. Patient has type 2 diabetes 3. Patient has not achieved desired HbA1c using combinations of >/= 2 oral hypoglycemic agents at maximally tolerated doses (this excludes those patients with significant contraindications to SU, metformin, or TZDs that would preclude using at least 2 agents in combination) And at least 1 of the following: 1. Documented true insulin allergy 2. Documented history of frequent or severe nocturnal hypoglycemia with insulin despite multiple attempts with various dosing regimens (including the use of insulin analogs) 3. Patient has a job that does not allow the use of insulin to treat diabetes (must be confirmed with patients place of employment)* *Congress has passed a new law which will allow the use of insulin for interstate commercial drivers who have diabetes, provided that stable control has been demonstrated. http://www.diabetes.org/advocacy-and-legalresources/discrimination/CDLFAQ. jsp Follow-up After initial prescription, patient must be reevaluated at least within 1-2 months by the prescribing clinician (initial prescription should only be written for up to 2 months including refills). Discontinue if there is a < 10% decrease in HbA1c (after 3-6 months of therapy). However, exenatide may be continued if patient has reached glycemic target regardless of the magnitude of drop in HbA1c Precautions Patients should be instructed to report any unexplained persistent severe abdominal pain which may or may not be accompanied by vomiting to their provider immediately. If pancreatitis is suspected, exenatide should be discontinued. Exenatide should not be restarted if pancreatitis is confirmed. Cautions Regarding Concomitant Medications Exenatide has not been studied in combination with meglitinides (e.g. repaglinide, nateglinide), or alpha-glucosidase inhibitors (e.g.	

			acarbose, miglitol) concurrent use should be avoided Exenatide should be used with caution in patients taking oral medications that require rapid gastric absorption Oral medications that are dependent on threshold concentrations for efficacy should be taken at least 1 hour before exenatide administration (e.g., antibiotics, oral contraceptives) Drugs that are administered with food should be taken with a meal or snack when exenatide is not administered Dosing: - Exenatide is administered with a sulfonylurea, metformin, or the combination. When exenatide is added to sulfonylurea therapy, a reduction in the dose of sulfonylurea may be considered to reduce the risk of hypoglycemia. Patients using metformin may continue to use their current dose. - Initial dose of exenatide is 5 mcg per dose administered twice daily at any time within the 60-minute period before the morning and evening meals. Exenatide should not be administered after a meal. If a dose is missed, the treatment regimen should be resumed with the next scheduled dose. - If the patient tolerated the initial dose and a dosage increase is indicated, exenatide can be increased to 10 mcg twice daily after 1 month of therapy. - Exenatide is injected subcutaneously in the thigh, abdomen, or upper arm. September 2008 VISN 20 P&T Committee Minutes	
CV350	EZETIMIBE	ZETIA	Ezetimibe (Zetia or Vytorin) National VA Criteria for Non-Formulary Use (Updated May 2008) Candidates for Ezetimibe (Patients who have met their LDL-C goal on statin monotherapy should NOT be switched to combination therapy with ezetimibe) A. In Combination with Statins: *VA/DoD Dyslipidemia Guideline recommends an LDL-C goal of 400 mg/dL and in familial dysbetalipoproteinemia. Avoid in patients with triglyceride levels >400 mg/dL 5 There is emerging evidence suggesting patients with common features of impaired fatty acid oxidation may have recurrence of their myopathic symptoms on ezetimibe as well as niacin, fibrates and statins. 6 For other possible LDL-C lowering strategies and considerations, refer to page 4. Refer to pages 4 and 5 for niacin dose titration. Criterion For Discontinuing Ezetimibe There is potential variability in response to cholesterol absorption inhibitors. Generally response to a new lipid treatment should be gauged at two follow-up clinic visits. If a patient does not experience a substantive response to addition of ezetimibe, usually a decrease in LDL-C by	NON-FORMULARY

			10-15% toward goal, ezetimibe should be discontinued. Safety Considerations a. Ezetimibe is not recommended in patients with moderate or severe liver impairment because the effects of increased exposure to ezetimibe are not known. b. Clinically significant elevation (>3 times upper limit of normal) in liver function tests were seen in a significantly greater number of patients receiving ezetimibe plus a statin (1.3%-2%) versus a statin alone (0.4%). When ezetimibe is used in combination with statins, LFTs must be monitored (see section 5 below). c. Several cases of myopathy have been reported in patients receiving high-dose statins upon initiation of ezetimibe. As a result, caution should be used when adding ezetimibe to statins, especially in patients more susceptible to statin myopathy (e.g., advanced age, frailty, female gender, drug-drug interactions, hypothyroidism, alcoholism, etc.). d. Fibrates work by increasing cholesterol excretion into the bile, which can lead to cholelithiasis. In an animal study, ezetimibe increased cholesterol in the gallbladder bile. Upon FDA approval of ezetimibe, the manufacturer recommended against combining ezetimibe with fibrates until human studies had been completed because of a potential for an increased risk of cholelithiasis. In a study published in 2005, 625 patients with no known coronary artery disease were randomized to receive placebo, fenofibrate 160 mg, ezetimibe 10 mg or the combination for 12 weeks. The combination grouped experienced the greatest mean percent LDL-C reduction. In the 48-week extension study, similar results were observed. Although there were no significant differences in planned or performed cholecystectomies between groups in either trial, the trials were not of sufficient size or duration to adequately compare gallstone development between groups. As a result, there is not sufficient evidence to conclude whether or not the combination will result in an increased risk of cholelithiasis or cholecystectomy. e. Triple therapy with statins, BAS or niacin, and ezetimibe is generally not recommended since efficacy and long term safety are uncertain. f. The combination of ezetimibe with BAS or niacin is generally not recommended since there are no published data demonstrating safety and efficacy of the combination, unless no other alternatives exist. In addition, the LDL-C lowering effect of ezetimibe may be reduced in the presence of BAS. g. All patients receiving statins.	

			including those receiving combination therapy with ezetimibe, should be informed regarding the recognition and reporting of any unexplained muscle pain, tenderness or weakness. h. For additional data on safety, including drug-drug interactions, see the ezetimibe monograph at http://www.pbm.va.gov or http://vaww.pbm.va.gov Dosage and Administration The manufacturer's recommended dose is 10 mg daily without regard to meals. However, some advocate using a 5 mg dose. In a pooled analysis of two-phase II studies, the LDL-C lowering response of 0.25 mg, 1 mg, 5 mg and 10 mg of ezetimibe (monotherapy) was examined in 432 patients for 12 weeks. The 5 mg dose reduced LDL-C by 15.7% and the 10 mg by 18.5% (P15% and 67.8% of those in the 10 mg group had reductions in their LDL-C of >15%. In another study, a small number of patients (n=8 in each group) were randomized to lovastatin 20 mg, lovastatin 20 mg + ezetimibe 5 mg, lovastatin 20 mg + ezetimibe 10 mg, lovastatin 20 mg + ezetimibe 20 mg or lovastatin 40 mg + ezetimibe 10 mg for 2 weeks. Addition of ezetimibe resulted in an additional reduction in LDL-C of 16-18% compared to lovastatin alone. There were no differences in LDL-C lowering response observed between 5, 10 or 20 mg of ezetimibe. Monitoring When ezetimibe is administered in combination with a statin, LFTs should be performed prior to initiation of therapy and according to the recommendations of the statin (e.g., simvastatin: within the first 12 weeks, and periodically thereafter). May 2008 VISN 20 P&T Committee	
GA301	FAMOTIDINE 20MG, 40MG TAB	PEPCID	Non-Formulary: no criteria for use	NON-FORMULARY
MS400	FEBUXOSTAT ORAL TAB	ULORIC	VA National Non-Formulary Criteria for Use Febuxostat (Uloric) VA Pharmacy Benefits Management Service Medical Advisory Panel and VISN Pharmacist Executives EXCLUSION CRITERIA (If one is checked, patient is NOT eligible) O Hypersensitivity or history of intolerance to febuxostat (or inactive tablet ingredients) O Asymptomatic hyperuricemia O Concomitant administration of drugs that are metabolized by xanthine oxidase (e.g., theophylline, mercaptopurine, azathioprine) INCLUSION CRITERIA FOR FEBUXOSTAT (MUST FULFILL THE FOLLOWING TO BE ELIGIBLE) O The patient is a candidate for the chronic treatment of gout, i.e. patient is hyperuricemic and has recurrent gouty attacks (= 2 acute	NON-FORMULARY

			attacks/year) or other manifestation of chronic gout (tophaceous disease, erosive gouty arthritis, or uric acid urolithiasis). O There is documentation of a lack of adequate response or contraindication to, or an inability to tolerate, appropriately dose-maximized trials of allopurinol1 and /or probenecid2. DOSING RECOMMENDATIONS The initial recommended starting dose of febuxostat is 40 mg daily; a dose of 80 mg daily is recommended for patients who do not achieve a serum urate < 6 mg/dl after 2 weeks of treatment at the lower dose. Febuxostat may be administered without regard to food. PRECAUTIONS AND WARNINGS As with other urate lowering agents, the initiation of febuxostat is associated with an increased risk for gouty flares; prophylaxis with a non-steroidal anti-inflammatory drug (or colchicine) during this period is recommended The combination of febuxostat and allopurinol may result in xanthinuria. Febuxostat is pregnancy category C; animal reproduction studies have shown an adverse effect on the fetus (increased neonatal mortality and a reduction in neonatal body weight gain). There are no adequate and well-controlled studies of febuxostat in human pregnancy, but potential benefits may warrant use of the drug in that population despite potential risks Febuxostat is excreted in the milk of rats. Although it is not known if febuxostat is excreted in human milk, caution should be exercised when febuxostat is administered to a nursing woman. Febuxostat should be used with caution in the following patients not studied in the clinical trials: Patients with greater than moderate kidney dysfunction (defined as serum creatinine > 1.7 mg/dl for women and > 2.0 mg/dl for men, or estimated glomerular filtration rate < 30 ml/min) Patients with end-stage renal disease on dialysis Patients with severe hepatic impairment (Child-Pugh Class C) The efficacy of febuxostat in the treatment of secondary hyperuricemia (an acquired disorder resulting from certain cancers, chemotherapy, various drugs, and other causes) has not been established. MONITORING RECOMMENDATIONS Liver function testing is recommended on initiation of febuxostat and periodically thereafter The urate therapeutic target range < 6.0 mg/dl is the most frequently utilized standard for effective treatment of gout and has been associated with reduced frequency of acute gout flares, deceased tophus size, and decreased detection of urate crystals in synovial fluid Overall, a higher rate of	

			cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke has been observed in febuxostat compared to allopurinol-treated patients although a causal relationship with febuxostat has not been established. Patients on febuxostat should be monitored for signs and symptoms of myocardial infarction and stroke. RECOMMENDATION FOR DISCONTINUATION Patient does not achieve a clinically significant reduction in serum urate within 6 months of initiation (i.e. the patient does not attain a serum urate reduction of adequate magnitude to reduce the frequency of acute gout flares and/or to favorably alter other manifestations of chronic gout). 1 FDA-approved dosing guidelines for allopurinol advocate upwards dose titration, starting from the minimal effective dose (100-200 mg daily), followed by dose increases of 100mg every week until a normal serum urate (= 6m g/dl) is achieved. Allopurinol 200-300 mg daily is typically sufficient for patients with mild gout; however, a dose of 400 to 600 mg daily may be required to control severe tophaceous disease. Allopurinol is FDA-approved for doses up to 800mg daily in the treatment of hyperuricemia in patients with gout who have normal renal function. FDA dosing guidelines advocate limiting the maximum allopurinol dose to 100mg daily when the creatinine clearance (CrCl) < 10 ml/min and to 200 mg daily when the CrCl is 10-20 ml/min, but do not specify a scale for dosing allopurinol in moderate renal dysfunction. Maximum serum urate lowering resulting from a stable dose of allopurinol occurs within 2-3 weeks. Allopurinol may increase the frequency of attacks during the first 6-12 months of therapy even if goal urate has been obtained; prophylactic doses of a NSAID or colchicine should be given concurrently during the first 3-6 months of therapy. Noncompliance with allopurinol and/or underdosing of the drug should not be misinterpreted as treatment failure. Inability to achieve a serum urate < 6 mg/dl should not be considered a treatment failure if acute flares are controlled or if other manifestations of chronic gout are positively influenced (allow up to 6 months). 2 Probenecid use should be avoided in patients who have a CrCl < 50 ml/min; use should also be avoided in patients who overexcrete urate (where 24 -hour urinary uric acid excretion is > 800 mg/day). Probenecid is initiated at 250 mg twice daily and can be titrated in 500 mg increments every 4 weeks to clinical response (maximum dose of 2-3 g/day). Patients on	

			probenecid should maintain good hydration by targeting a urine output of 2-3 L/day; alkalinization of the urine may be desirable early in therapy until goal urate is achieved and/or tophaceous deposits resolve. . PBM Oct 2009; VISN 20 P&T Nov 2009	
CV350	FENOFIBRATE ORAL	TRICOR	Fenofibrate (Tricor) is non-formulary, restricted to Endocrinology, Cardiology, Lipid Clinic, or local facility equivalent(s) as third-line therapy after failure or intolerance to niacin and gemfibrozil. May 2007	NON-FORMULARY
CN101	FENTANYL CITRATE ORAL LOZENGE	ACTIQ		NON-FORMULARY
CN101	FENTANYL/DROPERIDOL INJ	INNOVAR	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
TN410O	FERUMOXYTOL 30MG (IRON)/ML INJ	FERAHEME INJ	Non-Formulary: no criteria for use	NON-FORMULARY
AH600	FEXOFENADINE 60MG CAP, 180MG SA TAB	ALLEGRA	Non-Formulary: no criteria for use	NON-FORMULARY
MS900	FINGOLIMOD	GILENYA	NON-FORMULARY, CFU	NON-FORMULARY
BL116	FLOSEAL MATRIX	FLOSEAL MATRIX	Non-Formulary: no criteria for use	NON-FORMULARY
AN300	FLOXURIDINE INJ	FUDR	Non-Formulary: no criteria for use	NON-FORMULARY
DE200	FLUOCINOLONE OINT 0.025% 60GM	SYNALAR	Restricted to Dermatology or local equivalent	NON-FORMULARY
RE101	FLUTICASONE PROP 220MCG 120D ORAL INHL	FLOVENT	(1) Mometasone (Asmanex) is formulary, the first line oral steroid inhaler (2) Flunisolide (Aerobid) is formulary, second line. (3) All other oral corticosteroid inhalers are non-formulary. June 16th 2006 VISN 20 P&T Committee	NON-FORMULARY
RE109	FLUTICASONE/SALMETEROL DISKUS	ADVAIR	Non-Formulary: no criteria for use	NON-FORMULARY
CV350	FLUVASTATIN	LESCOL	NON-FORMULARY, CFU NON-FORMULARY, CFU	NON-FORMULARY

CV350	FLUVASTATIN IR AND SA ORAL TAB	LESCOL	Non-Formulary: no criteria for use	NON-FORMULARY
CV701	FORMOTEROL SOLN,INHL	PERFOROMIST	Non-Formulary: no criteria for use	NON-FORMULARY
RE109	FORMOTEROL/BUDESONIDE ORAL INHALER	SYMBICORT	Non-Formulary: no criteria for use	NON-FORMULARY
	FOSPROPOFOL	LUSEDRA	NON-FORMULARY	NON-FORMULARY
AM800	GANCICLOVIR ORAL	CYTOVENE	Restricted to Infectious Disease Service and Transplant Service, or local equivalents.	NON-FORMULARY
OP220	GATIFLOXACIN 0.3% OPHTHALMIC SOLUTION	ZYMAR	Restrictions per local facility	NON-FORMULARY
AM900	GATIFLOXACIN INJ	TEQUIN	VA National Fluoroquinolone Criteria for Use Patient Selection: Please note that this document discusses the most common indications for fluoroquinolone use. It is not intended to be a comprehensive list of all appropriate uses of fluoroquinolones. Urinary tract infections: Due to antimicrobial resistance, in many medical centers fluoroquinolones are the antimicrobial of choice for empiric treatment of urinary tract infections. For this indication, based on safety, efficacy and price ciprofloxacin is the fluoroquinolone of choice. Community-acquired pneumonia: Hospitalized patients: First line therapy is generally with the combined use of a macrolide and a beta-lactam agent active against penicillin-resistant Streptococcus pneumoniae (e.g., cefotaxime or ceftriaxone). Fluoroquinolones should generally be considered second line agents for treatment of beta-lactam allergic patients. Outpatients: Use of fluoroquinolones requires radiological evidence of pneumonia and should be consistent with guidelines. Other upper and lower respiratory tract infections: Fluoroquinolones are generally second or third line agents based on the likely or proven susceptibility of known or probable infectious agents. Safety concerns with fluoroquinolone therapy involve the use of these agents in specific populations. O Patients with a history of long QT syndrome, hypokalemia or who are receiving Class Ia or class III antiarrhythmic agents (quinidine, disopyramide, procainamide, sotalol, amiodarone, dofetilide, ibutilide) are predisposed to development of Torsades de Pointes or other cardiac arrhythmias. These arrhythmias have been reported with levofloxacin, gatifloxacin and moxifloxacin. These fluoroquinolones should be avoided in this patient population. O Disturbances of blood glucose, including symptomatic hypoglycemia and hyperglycemia, have been reported with all fluoroquinolones. The risk of dysglycemia is greatest in diabetic patients. However,	NON-FORMULARY

			hypoglycemia and particularly hyperglycemia have occurred in patients without a history of diabetes. Criteria for use of Levofloxacin - both IV and oral If the answer to either Indication for therapy or Identification of risk factors is yes the patient is eligible for levofloxacin therapy Indication for therapy Ventilator dependent pneumonia Y/N Healthcare associated pneumonia Y/N Identification of risk factors Patient at risk for P. aeruginosa; bronchectisis, cystic fibrosis, or previous antibiotic therapy within the past month? Y/N Patient shows no response to current antibiotic therapy? Y/N Levofloxacin dosage Healthcare associated/ventilator dependent pneumonia Normal renal function 750 mg IV daily* Impaired renal function Initial subsequent dosing Ccr 20 to 49 mL/min 750 mg 750 mg every 48 h Ccr 10 to 19 mL/min 750 mg 500 mg every 48 h Hemodialysis 750 mg 500 mg every 48 h CAPD 750 mg 500 mg every 48 h IV - intravenous, PO - orally * - patients may be transitioned to oral levofloxacin therapy when appropriate, either after receiving IV levofloxacin or other appropriate IV therapy. Local consensus protocols should be consulted for specific antibiotic choice(s) and for relevant approval processes in these circumstances. November 2006 VISN 20 P&T Committee	
AM900	GATIFLOXACIN ORAL	TEQUIN	VA National Fluoroquinolone Criteria for Use Patient Selection: Please note that this document discusses the most common indications for fluoroquinolone use. It is not intended to be a comprehensive list of all appropriate uses of fluoroquinolones. Urinary tract infections: Due to antimicrobial resistance, in many medical centers fluoroquinolones are the antimicrobial of choice for empiric treatment of urinary tract infections. For this indication, based on safety, efficacy and price ciprofloxacin is the fluoroquinolone of choice. Community-acquired pneumonia: Hospitalized patients: First line therapy is generally with the combined use of a macrolide and a beta-lactam agent active against penicillin-resistant Streptococcus pneumoniae (e.g., cefotaxime or ceftriaxone). Fluoroquinolones should generally be considered second line agents for treatment of beta-lactam allergic patients. Outpatients: Use of fluoroquinolones requires radiological evidence of pneumonia and should be consistent with guidelines. Other upper and lower respiratory tract infections: Fluoroquinolones are generally second or third line agents based on the likely or proven susceptibility of	NON-FORMULARY

			known or probable infectious agents. Safety concerns with fluoroquinolone therapy involve the use of these agents in specific populations. O Patients with a history of long QT syndrome, hypokalemia or who are receiving Class Ia or class III antiarrhythmic agents (quinidine, disopyramide, procainamide, sotalol, amiodarone, dofetilide, ibutilide) are predisposed to development of Torsades de Pointes or other cardiac arrhythmias. These arrhythmias have been reported with levofloxacin, gatifloxacin and moxifloxacin. These fluoroquinolones should be avoided in this patient population. O Disturbances of blood glucose, including symptomatic hypoglycemia and hyperglycemia, have been reported with all fluoroquinolones. The risk of dysglycemia is greatest in diabetic patients. However, hypoglycemia and particularly hyperglycemia have occurred in patients without a history of diabetes. Criteria for use of Levofloxacin - both IV and oral If the answer to either Indication for therapy or Identification of risk factors is yes the patient is eligible for levofloxacin therapy Indication for therapy Ventilator dependent pneumonia Y/N Healthcare associated pneumonia Y/N Identification of risk factors Patient at risk for P. aeruginosa; bronchectisis, cystic fibrosis, or previous antibiotic therapy within the past month? Y/N Patient shows no response to current antibiotic therapy? Y/N Levofloxacin dosage Healthcare associated/ventilator dependent pneumonia Normal renal function 750 mg IV daily* Impaired renal function Initial subsequent dosing Ccr 20 to 49 mL/min 750 mg 750 mg every 48 h Ccr 10 to 19 mL/min 750 mg 500 mg every 48 h Hemodialysis 750 mg 500 mg every 48 h CAPD 750 mg 500 mg every 48 h IV - intravenous, PO - orally * - patients may be transitioned to oral levofloxacin therapy when appropriate, either after receiving IV levofloxacin or other appropriate IV therapy. Local consensus protocols should be consulted for specific antibiotic choice(s) and for relevant approval processes in these circumstances. November 2006 VISN 20 P&T Committee	
AN900	GEFITINIB ORAL TAB	IRESSA	VA National Criteria for Non-Formulary Use Of Gefitinib Adopted by VISN 20 March, 2004 Gefitinib 250mg once a day may be used according to the following criteria: 1. Palliative treatment of locally advanced or metastatic non-small cell lung cancer 2. Progressed on or intolerant to two previous chemotherapy regimens, including platinum- and docetaxel based (either	NON-FORMULARY

			concurrent therapy or sequential) therapies as well as other combinations utilized in first and second line treatment strategies. 3. Disease-related symptoms will be measured by the Lung Cancer Subscale (LCS)* of the Functional Assessment of Cancer Therapy for-Lung Cancer (FACT-L). A score of >/= 24 on the LCS indicates disease-related symptoms. 4. Patient understands that the treatment is for palliation only. 5. Prior to gefitinib use specific target symptoms are evaluated, and treatment with proven benefit in managing these symptoms is optimized (oxygen, opiates for shortness of breath or pain, bronchodilators, cough suppressants, radiation therapy for collapsed lung). If symptoms are not adequately controlled or side effects from therapies are not tolerated, then consider the use of gefitinib. 6. Performance status of 0-2 (ambulatory) 7. Prescribing should be limited to 30 days per prescription From August 19, 2005 VISN P&T Committee minutes: Recent data have shown no survival advantage for patients treated with gefitinib when compared to placebo in patients with locally advanced or metastatic non-small cell lung cancer who had already received platinum-based and docetaxel chemotherapy regimens. To reflect this, the manufacturer, AstraZeneca, has made changes in product labeling and distribution. Effective September 15, 2005, gefitinib will only be available from a single specialty pharmacy provider, Priority Healthcare, through the Iressa Access Program. The limited distribution plan will allow the following patients to receive gefitinib: (1) patients currently receiving and benefiting from gefitinib; (2) patients who have previously received and benefited from gefitinib; and patients previously enrolled in or new patients in non-Investigational New Drug (Non-IND) clinical trials approved by an IRB prior to June 17, 2005. In the future, new patients may be able to obtain gefitinib if AstraZeneca makes it available under an IND. There will be no new patient starts after August 1, 2005 unless patients are enrolled in a non-IND clinical trial approved by an IRB prior to June 17, 2005.	

HS502	GLIMEPIRIDE ORAL	AMARYL	Glimepiride is non-formulary, restricted to patients who meet one of the following criteria: 1) patients in whom the use of an extended-release formulation is being considered due to potential cost-savings, 2) as a third-line alternative after glyburide and glipizide in patients who experience hypoglycemia on these two agents, but otherwise have good glycemic control, or 3) patients with inadequate blood glucose control defined as an HbA1c > 8 who have failed an adequate trial of glyburide due to poor compliance with a BID regimen.	NON-FORMULARY
OP900	GLYCERIN 50% OPH SOLN	OSMOGLYN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
PH000	GLYCERIN,ANHYDROUS	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
DE900	GLYCERIN/MINERAL OIL/PHENOL 1% LIQUID,TOP	P&S LIQUID	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
MS190	GOLIMUMAB INJ	SIMPONI	Non-Formulary: no criteria for use	NON-FORMULARY
AM700	GRISEOFULVIN ORAL	GRISACTIN	Non-Formulary: no criteria for use	NON-FORMULARY

DE900	HAMAMELIS WATER TOP LIQUID (OTC)	WITCH HAZEL	Non-Formulary: no criteria for use	NON-FORMULARY
RS202	HEMORRHOIDAL/HC RTL OINT	ANUSOL HC	Non-Formulary: no criteria for use	NON-FORMULARY
IM100	HPV BIVALENT VACCINE	CERVARIX	NON-FORMULARY	NON-FORMULARY
IM000	HPV QUADRIVALENT VACCINE	HPV QUADRIVALENT VACCINE	NON-FORMULARY	NON-FORMULARY
XX000	HYALURONIDASE INJ	AMPHADASE	Non-Formulary: no criteria for use	NON-FORMULARY
PH000	HYDROCHLORIC ACID LIQUID	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
RS202	HYDROCORTISONE RECTAL SUPPOSITORY	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AH500	HYDROXYZINE HCL 25MG TAB	ATARAX	Non-Formulary: no criteria for use	NON-FORMULARY
AH500	HYDROXYZINE HCL 50MG TAB	ATARAX	Non-Formulary: no criteria for use	NON-FORMULARY
MS900	HYLAN G-F 20 INJ (SYNVISC)	SYNVISC	Synvisc and Hyalgan are non-formulary, restricted to Rheumatology and Orthopedics Services for the treatment of pain in osteoarthritis (OA) of the knee in patients who meet the following national criteria: VA National Criteria for Non-Formulary Use of Hylan G-F 20 (Synvisc) and Sodium Hyaluronate (Hyalgan): Intra-Articular Administration for Osteoarthritis of the Knee The intra-articular (IA) administration of hyaluronic acid or hylan (cross-linked hyaluronan chains) is referred to as viscosupplementation. There are currently five products available in the US. These products are categorized as Biologic Devices by the FDA and can be considered for use in patients with OA of the knee who meet the following criteria. It is strongly recommended that the use of these agents be limited to specialists in Orthopedics, Rheumatology and Physical Medicine and Rehabilitation. (For details, refer to the hyaluronan/hylan review at www.pbm.va.gov or http://vaww.pbm.va.gov). EXCLUSION CRITERIA (If one is selected, patient is not eligible) o Known hypersensitivity or allergy to hyaluronate preparationsa o Knee joint infection, skin disease or infection in the area of the injection site a Orthvisc is contraindicated in patients with an allergy to avian proteins, feathers or eggs. INCLUSION CRITERIA (All must be selected for patient to be eligible) o Documented symptomatic (pain/stiffness) OA of the knee which interferes with functional activities (e.g. ambulation, prolonged standing, etc.) and/or is associated with significant pain. o Adequate trial (e.g. 2 to 3 months) of non-pharmacologic measures, as appropriate, (e.g. cane/crutches, bracing/orthotics, weight loss, physical therapy/exercise) has not resulted in adequate	NON-FORMULARY

			improvement in pain/function o Therapeutic trial of at least 3 analgesics (e.g. acetaminophen, topical capsaicin or topical NSAIDs, oral NSAIDs and other oral analgesics [e.g. tramadol] or narcotic analgesics [in patients with severe pain]) has not resulted in adequate improvement in pain/function; or patient is unable to tolerate or is not a candidate for NSAIDs or other oral analgesics. o Intra-articular corticosteroids have not resulted in adequate improvement in pain/function or there are compelling reasons to avoid IA corticosteroids. o Patient and/or provider have elected to continue conservative (nonsurgical) treatment for OA. PRECAUTIONS o There is some evidence to suggest that patients with more advanced stages of OA and near complete loss of joint space may be less likely to benefit from this therapy. o All HA or Hylan products are for intra-articular use only. o The origin of hyaluronic acid for Hyalgan, Orthovisc, Supartz and Synvisc is from avian sources (rooster combs). Labeling for Hyalgan, Supartz and Synvisc suggest administering with caution in those patients with a known allergy to avian proteins, feathers or eggs. However, Orthovisc is contraindicated in these individuals. Euflexxa is not derived from avian sources and can be used in patients with an allergy to avian proteins. o The safety/efficacy of concomitant administration of IA HA or hylan with other IA agents has not been established. o The safety/efficacy of administering these agents in pregnant women has not been established. DOSAGE AND ADMINISTRATION o Inta-articular administration of HA or hylan should be performed by a physician/provider who is technically proficient at administering drugs via the IA route. o Strict aseptic administration technique must be used. o Disinfectants containing quaternary ammonium salts (e.g. benzalkonium chloride or benzethonium chloride) should not be used for skin preparation as hyaluronic acid can precipitate under such conditions. May use isopropyl alcohol or povidone-iodine solutions to thoroughly clean site. o Remove joint effusion, if present, before injecting HA or hylan. o Subcutaneous lidocaine or other local anesthetic may be injected prior to IA administration of HA or hylan. Euflexxa Hyalgan Orthovisc # Inject/Course 3 3 or 5 3 or 4 Response 3 months* 3 inj-60 days* 6 months 5 inj- 6 months Supartz Synvisc Synvisc-One # Inject/Course 3 or 5 3 1 Response 3 inj-90 days* 5 inj- 6 months 6 months 6 months *Duration of study follow-up RECOMMENDED

			MONITORING/PATIENT INFORMATION o Transient pain and/or swelling of the injected joint have been reported after intra-articular administration of these agents. o As with any invasive procedure, it is recommended that patients avoid strenuous activity (e.g. more than 1 hour) or prolonged weight-bearing activities (e.g. jogging or tennis) within 48 hours of procedure. o Rare, anaphylactoid/allergic reactions have been reported with Hyalgan o Pseudosepsis or severe acute inflammatory reactions (SAIR) has been reported with Synvisc. Typically with the second or third injection in a course or with subsequent courses. REPEAT COURSES o There is evidence to support administering repeat courses of Hyalgan or Synvisc in those patients having experienced a beneficial response with their first course. However, the risk for adverse events does appear to increase in those given repeat courses with Synvisc but not Hyalgan. There is limited safety data for repeat Synvisc-Oner courses. The efficacy/safety of giving repeat courses using the other available products has not been established. o Repeat courses should not be administered within 6 months of the last injection. VISN 20 P&T Committee Jan 2010 .	
AU350	HYOSCYAMINE SULFATE - SL, RR AND SA DOSAGE FORMS	LEVSIN	Non-Formulary: no criteria for use	NON-FORMULARY
HS900	IBANDRONATE IV INJ	BONIVA	Non-Formulary: no criteria for use	NON-FORMULARY
AN500	IBANDRONATE ORAL TAB	BONIVA	Non-Formulary: no criteria for use	NON-FORMULARY
OP203	IDOXURIDINE 0.1% OPHTH SOLN	IDU	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

OP203	IDOXURIDINE 0.5% OPHTH OINT	IDU	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CN709	ILOPERIDONE	FANAPT	NON-FORMULARY	NON-FORMULARY
CV490	ILOPROST	VENTAVIS	NON-FORMULARY, CFU	NON-FORMULARY
	Immune Globulin Subcutaneous (Human) Liquid 20%	Hizentra	NON-FORMULARY	NON-FORMULARY
MS102	INDOMETHACIN SUPP 50MG	INDOCIN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
IM600	INFLIXIMAB INJ	REMICADE	Infliximab is restricted to: (1) For Crohn's disease, restricted to gastroenterologist or local facility equivalent for patients who have failed or are intolerant to conventional therapies, and whose only remaining option is surgery; (2) For Fistulizing Crohn's disease, restricted to gastroenterologist or local facility equivalent to be used (a) for patients with severe cases as first-line therapy for patients who will be started on concurrent mercaptopurine or azathioprine or as second-line therapy for patients who have failed mercaptopurine or azathioprine or (b) for patients with	NON-FORMULARY

			mild cases as second-line therapy for patients who have failed or are intolerant to conventional therapies (October 1999) (3) For Rheumatoid arthritis, follow National Criteria: National PBM Drug Criteria for Use for INFLIXIMAB (REMICADE) VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel Consider INFLIXIMAB As MONOTHERAPY if: - Documented contraindications, intolerance (toxicity) and/or suboptimal response to an adequate trial of MTX; AND - Documented contraindications, intolerance and/or suboptimal response to 1 or more standard DMARDS at standard target dose (unless significant toxicity limited the dose tolerated), regardless of whether they were prescribed sequentially or in combination: oral/injectable gold, hydroxychloroquine, sulfasalazine, penicillamine, azathioprine, leflunomide As COMBINATION THERAPY with MTX if: - Documented suboptimal response with full or maximally tolerated doses of MTX CRITERIA FOR ELIGIBILITY*: * Each patient's risk versus benefit should be carefully considered before initiating therapy (or continuing therapy) in instances where safety and efficacy have not been established (See Table 4). Choice of therapy should be based on physician discretion and clinical judgment. 1. Diagnosis of RA as defined by the American College of Rheumatology (ACR); AND 2. Active RA despite full and adequate treatment with 1 or more standard DMARDs at standard or maximally tolerated dose; AND 3. Baseline monitoring parameters within normal limits (See Table 5). CRITERIA FOR EXCLUSION: 1. MTX naive - If a patient has failed to demonstrate an adequate response to a single DMARD other than MTX, MTX should be initiated with doses up to 25 mg/week (as tolerated) for at least 3 months, with or without other DMARDs; OR 2. If a patient has previously achieved remission on a given DMARD, he or she should be restarted on this previously effective DMARD prior to use of etanercept; OR 3. Contraindications to infliximab. (See Table 3). CRITERIA FOR CONTINUATION: After initiation of an agent, adequate response with decreased disease activity such as improvement in severity of affected joints or resolution of flares/decrease in flares within 8-12 weeks based on clinical judgment and quantitative measurements, including: 1. Improvement in validated quantitative measures of response such as the Health Assessment Questionnaire (HAQ), visual analog scales	

			(VAS), Likert scales, joint tenderness and/or swelling, and laboratory data (ESR, CRP); AND 2. Improvement in the DAS score > 1.2; OR 3. Achievement of a DAS28 score of < 3.2; OR 4. > 20% improvement according to ACR 20% response criteria 5. Monitoring parameters at follow-up MUST be within normal limits (See Table 5). CRITERIA FOR WITHDRAWAL OF THERAPY: 1. Inefficacy - Inadequate response (despite confirmed compliance) within 8-12 weeks after starting treatment at the recommended dosing schedule (See Table 2); OR 2. Loss of efficacy/unacceptable disease activity - Ongoing disease activity after 3 consecutive months of maximum therapy despite confirmed compliance (i.e., Repetitive flares; progressive joint damage);OR 3. Development of drug-related toxicity or adverse events (See Tables 6 and 7). VISN 20 P&T Committee February 2009 http://vaww.apps.cmop.va.gov/PBMIntranetWEbSiteArchive/criteria/Criteria%20for%20Use%20for%20Leflunomide%20and%20Biologic%20DMARDs.pdf (4) For severe spondyloarthropathies, either infliximab or etanercept may be used as primary therapy at the discretion of the rheumatologist. Etanercept should remain the first choice due to its relative ease of administration and lower cost. (June 2003) Alefacept, Etanercept, Efalizumab and Infliximab Non-Formulary Criteria for Psoriasis Use Alefacept, etanercept, efalizumab and infliximab remain non-formulary for the treatment of severe psoriasis or psoriatic arthritis, restricted to physicians experienced in treating these indications such as Rheumatology, Dermatology, or local facility equivalent. Patients must meet all of the following criteria: 1. Patient is an adult > 18 years of age who has chronic (> 6 months) severe plaque psoriasis (for using any biologics) or psoriatic arthritis (for etanercept). Criteria for severe psoriasis: all four of the following: a. Disease is disabling or impairs the patient???s quality of life (self-reported), including the ability to work and activities of daily living AND b. Disease does not have a satisfactory response to treatments that have minimal risks AND c. The patient is willing to accept life-altering adverse effects to achieve less disease or no disease AND d. More than 10% of body surface is involved or other factors apply (patient???s attitude about disease; location of disease [e.g., face, hands, fingernails, feet, genitals]; symptoms [e.g., pain, tightness, bleeding, or severe itching]; arthralgias or arthritis). 2. Patient is a candidate for

			systemic antipsoriatic therapy or ultraviolet therapy, and has documented inaccessibility to ultraviolet therapy OR documented inadequate response, contraindication, intolerance, or hypersensitivity to methotrexate and, if available, ultraviolet therapy (PUVA or UVB) with or without oral retinoids (e.g., acitretin). 3. Patient has no contraindications to biologic therapy or other condition that would preclude the use of biologic agents. 4. No concurrent live or live-attenuated vaccines during therapy. 5. No concurrent immunosuppressive therapy except those used in the treatment of psoriasis. Ultraviolet therapy with or without retinoids is considered by experts to be safe to use with biologic agents, although published reports of such combination therapy are lacking at this time. Methotrexate is approved for concurrent use with etanercept and infliximab. Justification for any concurrent use of systemic or other immunosuppressive antipsoriatic therapy with biologic agents (such as for transitioning or potential additive effects in partial responders) should be clearly documented. Current prescribing information for the biologics advises against such combinations. Therefore, clinicians should weigh the potential risks and benefits before deciding to use concurrent ultraviolet, systemic, or other immunosuppressive therapy with biologics. November 19, 2004 VISN 20 P&T Committee	
HS501	INSULIN LENTE HUMAN 100 U/ML INJ (OTC)	NOVOLIN	Restricted to Endocrinology Service or local facility equivalent for patients who are allergic to NPH insulin or its components. September 2003	NON-FORMULARY
HS501	INSULIN LISPRO 100U/ML INJ	HUMALOG	Restricted to patients who meet the following criteria: A. Patient selection: Patient must meet one of the following: 1. Type I diabetic with inadequate response (HgbA1c >8.0) 2. Patient should demonstrate inadequate control with current insulin therapy (a) Type I diabetic with repeated hypoglycemic episodes (b) Type I diabetic who has attempted tight control but failed B. Rapid acting insulin is substituted for regular insulin; because of its rapid onset of action, patients need to inject rapid acting insulin immediately prior to eating. C. Blood glucose should be monitored frequently after switching from regular insulin. D. Dose modifications of concurrent longer-acting insulin preparations may be necessary. August 1998, August 2003 VISN P&T Committee	NON-FORMULARY

HS501	INSULIN, INHALED	EXUBERA	VA Non-Formulary Criteria for Use of Inhaled Insulin (Exubera) The following 2 criteria must be met: 1. Restricted to endocrinologist, diabetologist or local facility equivalent. Provider is experienced in managing diabetic patients on insulin. 2. Patient must have baseline spirometry and diffusing capacity for carbon monoxide (DLCO). AND at least 1 of the following: 1. Severe persistent injection site problems such as lipohypertrophy OR 2. Works in an environment that does not allow needles (e.g., prison guard). VA Exclusion Criteria: 1. Patients who smoke or who have recently quit smoking within the last 6 months of starting inhaled insulin. 2. Known respiratory disorders or abnormal pulmonary function tests.1 3. CHF requiring pharmacologic therapy.2 1 Studies in patients with COPD and asthma are in progress; however, preliminary data from these trials show that the rate of non-severe pulmonary exacerbations was increased in the inhaled insulin groups versus the comparator groups. 2 These patients were excluded from the Phase 3 clinical trials. Use in Patients with Needle Aversion: While not included in the criteria for use, it is appreciated that there may be exceptional circumstances where inhaled insulin may be needed for patients with a psychological aversion to needles. Such a decision to use inhaled insulin must be made on a case-by-case basis. Prior to considering inhaled insulin the following is recommended: - Patient train with a VA Diabetes Educator consultation with a psychologist. - Offer a trial of insulin pens, smaller gauge needles, and other assistive devices. - Patient must demonstrate and agree to self-monitoring of blood glucose. If the patient ultimately requires the addition of basal insulin, conversion of pre-meal inhaled to injectable insulin should be made once the patient is stabilized on basal insulin and is comfortable with injection. Pulmonary Function Monitoring: Baseline spirometry and diffusing capacity for carbon monoxide (DLCO) are required before beginning treatment AND within the first 6 months then annually thereafter. In patients that have a > 20% decline in FEV1 from baseline or a DLCO that declines and becomes abnormal according to the standards of the local PFT laboratory, pulmonary functions tests should be repeated. If FEV1 or DLCO abnormalities are confirmed, inhaled insulin should be discontinued. For patients with lesser declines in FEV1 or DLCO, more frequent pulmonary function monitoring may be required and discontinuation of inhaled insulin	NON-FORMULARY

			considered. Dosage and Administration: - 1mg blister of inhaled insulin is approximately equal to 3 units of subcutaneous regular human insulin. - 3mg blister of inhaled insulin is approximately equal to 8 units of subcutaneous regular human insulin. - Three 1mg doses do not equal one 3mg dose. It was found that Cmax and AUC of three 1mg blisters were approximately 30% and 40% higher respectively compared to one 3mg blister. - Three 1mg doses should not be substituted for one 3mg dose. If the 3mg blisters become temporarily unavailable for a patients stabilized on a regimen that included the 3mg blisters, two 1mg blisters may be substituted for one 3mg blister. * Insert unit dose blister into inhaler. Pump handle of inhaler, press button to pierce blister. Insulin powder is dispersed into chamber and ready for inhalation. * Administer no more than 10 minutes prior to meals. * Patients with type 1 diabetes will still require injectable basal insulin. Initial dosing may be based on weight (actual body weight) using the guidelines in table below. Additional factors that should be taken into consideration when determining a starting dose include patient???s current glycemic control, previous response to insulin, dietary and exercise habits. Further dose adjustment should be based on results of blood glucose monitoring. Initial dosing recommendations: Pt weight Initial dose/meal # 1mg blisters/dose # 3mg blisters/dose 30 - 39.9kg 1 mg per meal 1 - 40 - 59.9kg 2 mg per meal 2 - 60 - 79.9kg 3 mg per meal - 1 80 - 99.9kg 4 mg per meal 1 1 100 -119.9kg 5 mg per meal 2 1 120-139.9kg 6 mg per meal - 2 January 2007	
IM700	INTERFERON ALFACON-1INJ	INFERGEN	Non-Formulary: no criteria for use	NON-FORMULARY
MS102	INTRANASAL KETOROLAC	SPRIX	NON-FORMULARY	NON-FORMULARY
MS102	INTRAVENOUS IBUPROFEN	CALDOLOR	NON-FORMULARY	NON-FORMULARY
IM900	IPILIMUMAB	YERVOY	NON-FORMULARY	NON-FORMULARY
CV250	ISOSORBIDE DINITRATE 5MG SL TAB	ISORDIL	Non-Formulary: no criteria for use	NON-FORMULARY
OP106	ISOSORBIDE ORAL SOLN	ISMOTIC	Non-formulary, limited to short-term use (eg post-op, acute IOP elevation) May 2007	NON-FORMULARY
GA400	KAOLIN/PECTIN SUSPENSION 180ML	KAO-PECTATE	Non-Formulary: no criteria for use	NON-FORMULARY
PH000	KARAYA GUM POWDER	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
XA604	KARAYA POWDER (OTC)	N/A	Non-Formulary: no criteria for use	NON-FORMULARY

CN400	LACOSAMIDE	VIMPAT	NON-FORMULARY	NON-FORMULARY
PH000	LACTOSE PWDR	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
CN400	LAMOTRIGINE TAB,SA,24HR (EXTENDED RELEASE)	LAMICTAL XR	Non-Formulary: no criteria for use	NON-FORMULARY
HS701	LANREOTIDE INJ,SUSP,SA	SOMATULINE DEPOT	Non-Formulary: no criteria for use	NON-FORMULARY
GA900	LANSOPRAZOLE ORAL	PREVACID	Non-Formulary: no criteria for use	NON-FORMULARY
OP109	LATANOPROST OPH SOLN	XALATAN	Latanoprost and bimatoprost are non formulary, restricted to patients who cannot be adequately treated with the first line ophthalmic prostaglandin, travoprost. Bimatoprost is 2nd line, latanoprost is 3rd line. August 2003 VISN 20 P&T Committee	NON-FORMULARY
DE820	LCD SHAMPOO	LCD SHAMPOO	Non-Formulary: no criteria for use	NON-FORMULARY
MS109	LEFLUNOMIDE ORAL	ARAVA	National PBM Drug Criteria for Use: LEFLUNOMIDE (ARAVA) VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel Consider LEFLUNOMIDE As MONOTHERAPY if: - Documented contraindications, intolerance (toxicity) and/or suboptimal response to an adequate trial of MTX AND - Documented contraindications, intolerance and/or suboptimal response to 1 or more standard DMARDS at standard target dose (unless significant toxicity limited the dose tolerated), regardless of whether they were prescribed sequentially or in combination: oral/injectable gold, hydroxychloroquine, sulfasalazine, penicillamine, azathioprine. As COMBINATION THERAPY with MTX if: - Documented suboptimal response with full or maximally tolerated doses of MTX CRITERIA FOR ELIGIBILITY*: * Each patient's risk versus benefit should be carefully considered before initiating therapy (or continuing therapy) in instances where safety and efficacy have not been established (See Table 4). Choice of therapy should be based on physician discretion and clinical judgment. 1. Diagnosis of RA as defined by the American College of Rheumatology (ACR); AND 2. Active RA despite full and adequate treatment with > 1 standard DMARDs at standard or maximally tolerated dose; AND 3. Baseline monitoring parameters within normal limits (See Table 5). CRITERIA FOR EXCLUSION: 1. MTX naive - If a patient has failed to demonstrate an adequate response to a single DMARD other than MTX, MTX should be initiated with doses up to 25mg/week (as tolerated) for at least 3 months, with or without other DMARDs; OR 2. If a patient has	NON-FORMULARY

			previously achieved remission on a given DMARD, he or she should be restarted on this previously effective DMARD prior to use of leflunomide; OR 3. Contraindications to leflunomide. (See Table 3). CRITERIA FOR CONTINUATION: After initiation of an agent, adequate response with decreased disease activity such as improvement in severity of affected joints or resolution of flares/decrease in flares within 4-12 weeks based on clinical judgment and quantitative measurements, including: 1. Improvement in validated quantitative measures of response such as the Health Assessment Questionnaire (HAQ), visual analog scales (VAS), Likert scales, joint tenderness and/or swelling, and laboratory data (ESR, CRP); AND 2. Improvement in the DAS score > 1.2; OR 3. Achievement of a DAS28 score of < 3.2; OR 4. > 20% improvement according to ACR 20% response criteria 5. Monitoring parameters at follow-up MUST be within normal limits (See Table 5). CRITERIA FOR WITHDRAWAL OF THERAPY: 1. Inefficacy - Inadequate response (despite confirmed compliance) within 4-12 weeks after starting treatment at the recommended dosing schedule (See Table 2); OR 2. Loss of efficacy/unacceptable disease activity - Ongoing disease activity after 3 consecutive months of maximum therapy despite confirmed compliance (i.e., Repetitive flares; progressive joint damage);OR 3. Development of drug-related toxicity or adverse events (See Tables 6 and 7). http://vaww.apps.cmop.va.gov/PBMIntranetWEbSiteArchive/criteria/Criteria%2 0for%20Use%20for%20Leflunomide%20and%20Biologic%20DMARDs.pdf VISN 20 P&T Committee February 2009 .	
DE900	LEMON GLYCERIN SWABS	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AN500	LEUPROLIDE ACETATE IMPLANT	VIADUR	Leuprolide acetate implant (Viadur) is non-formulary, restricted to patients with metastatic prostate cancer who require hormonal manipulation therapy for at least 12 months and have refused or are not candidates for an orchiectomy AND have demonstrated tolerability and a response (a decrease in serum testosterone to castrate levels (	NON-FORMULARY
AN500	LEUPROLIDE INJ DEPOT	LUPRON	Non-Formulary: no criteria for use	NON-FORMULARY
RE101	LEVALBUTEROL ORAL INHALER	XOPENEX	Non-Formulary: no criteria for use	NON-FORMULARY
AN400	LEVAMISOLE ORAL	ERGAMISOL	Restricted to Oncology Service or local equivalent	NON-FORMULARY

OP900	LEVOCABASTINE HCL OPH SUSP	LIVOSTIN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
AH105	LEVOCETIRIZINE DIHYDROCHLORIDE 5 MG TAB	XYZAL	Non-Formulary: no criteria for use	NON-FORMULARY
CN500	LEVODOPA 250MG CAP, 500MG TAB	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AM900	LEVOFLOXACIN ORAL	LEVAQUIN	VA National Fluoroquinolone Criteria for Use Patient Selection: Please note that this document discusses the most common indications for fluoroquinolone use. It is not intended to be a comprehensive list of all appropriate uses of fluoroquinolones. Urinary tract infections: Due to antimicrobial resistance, in many medical centers fluoroquinolones are the antimicrobial of choice for empiric treatment of urinary tract infections. For this indication, based on safety, efficacy and price ciprofloxacin is the fluoroquinolone of choice. Community-acquired pneumonia: Hospitalized patients: First line therapy is generally with the combined use of a macrolide and a beta-lactam agent active against penicillin-resistant Streptococcus pneumoniae (e.g., cefotaxime or ceftriaxone). Fluoroquinolones should generally be considered second line agents for treatment of beta-lactam allergic patients. Outpatients: Use of fluoroquinolones requires radiological evidence of pneumonia and should be consistent with guidelines. Other upper and lower respiratory tract infections: Fluoroquinolones are generally second or third line agents based on the likely or proven susceptibility of known or probable infectious agents. Safety concerns with fluoroquinolone therapy involve the use of these agents in specific populations. O Patients with a history of long QT syndrome, hypokalemia or who are receiving Class Ia or class III antiarrhythmic agents (quinidine, disopyramide, procainamide, sotalol,	NON-FORMULARY

			amiodarone, dofetilide, ibutilide) are predisposed to development of Torsades de Pointes or other cardiac arrhythmias. These arrhythmias have been reported with levofloxacin, gatifloxacin and moxifloxacin. These fluoroquinolones should be avoided in this patient population. O Disturbances of blood glucose, including symptomatic hypoglycemia and hyperglycemia, have been reported with all fluoroquinolones. The risk of dysglycemia is greatest in diabetic patients. However, hypoglycemia and particularly hyperglycemia have occurred in patients without a history of diabetes. Criteria for use of Levofloxacin - both IV and oral If the answer to either Indication for therapy or Identification of risk factors is yes the patient is eligible for levofloxacin therapy Indication for therapy Ventilator dependent pneumonia Y/N Healthcare associated pneumonia Y/N Identification of risk factors Patient at risk for P. aeruginosa; bronchectisis, cystic fibrosis, or previous antibiotic therapy within the past month? Y/N Patient shows no response to current antibiotic therapy? Y/N Levofloxacin dosage Healthcare associated/ventilator dependent pneumonia Normal renal function 750 mg IV daily* Impaired renal function Initial subsequent dosing Ccr 20 to 49 mL/min 750 mg 750 mg every 48 h Ccr 10 to 19 mL/min 750 mg 500 mg every 48 h Hemodialysis 750 mg 500 mg every 48 h CAPD 750 mg 500 mg every 48 h IV - intravenous, PO - orally * - patients may be transitioned to oral levofloxacin therapy when appropriate, either after receiving IV levofloxacin or other appropriate IV therapy. Local consensus protocols should be consulted for specific antibiotic choice(s) and for relevant approval processes in these circumstances. November 2006 VISN 20 P&T Committee	

CN102	LEVOMETHADYL ACETATE HCL SOLN	ORLAAM	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
GU900	LEVONORGESTREL 20 uGM IUD	MIRENA	Not provided by VA Pharmacy Service.	NON-FORMULARY
CN101	LEVORPHANOL ORAL	DROMORAN	Available as an alternative for the management of chronic non-malignant pain for patients whom fail morphine or methadone.	NON-FORMULARY
TN503	L-GLUTAMINE 15 GM PACKET	N/A	Oxandrolone is non-formulary, restricted to the following criteria (a specific Northwest Network oxandrolone request form was developed by Puget Sound): 1. Restricted to use in spinal cord injury patients, prescribed by SCI attending or local facility equivalent. 2. Patients must have a documented non-healing pressure ulcer with no change in healing while receiving adequate nutritional support (high calorie and high protein diet) for the previous eight weeks. 3. Patients must have nutritional compromise demonstrated by albumin < 3.4 4. Patients must have nutritional compromise demonstrated by > 10% loss of body weight in the previous six months. 5. L-glutamine packets (one packet per day) will be used with oxandrolone for the first month of treatment only. 6. Oxandrolone therapy is limited to 12 weeks. May 2007	NON-FORMULARY

NT300	LIDOCAINE 10% ORAL AEROSOL	N/A	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
DE700	LIDOCAINE 2.5% OINT	XYLOCAINE	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CN204	LIDOCAINE 3.5% Opthalmic Gel	AKTEN	NON-FORMULARY	NON-FORMULARY

NT300	LIDOCAINE 5% DENTAL OINT	N/A	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
NT300	LIDOCAINE 5% DENTAL SOLN	N/A	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
NT300	LIDOCAINE HCL 2% ORAL SOLN	XYLOCAINE	Non-Formulary: no criteria for use	NON-FORMULARY
DE700	LIDOCAINE TOPICAL PATCH	LIDODERM	Lidocaine patches (Lidoderm) are non-formulary, restricted to use for documented cases of postherpetic neuralgia following failure, intolerance, or contraindications to tricyclic antidepressants, capsaicin cream, and gabapentin	NON-FORMULARY
AP300	LINDANE 1% LOTION 60ML	KWELL	Non-Formulary: no criteria for use	NON-FORMULARY
AP300	LINDANE 1% SHAMPOO 60ML	KWELL	Non-Formulary: no criteria for use	NON-FORMULARY
AP300	LINDANE CREAM	KWELL	Non-Formulary: no criteria for use	NON-FORMULARY
HS851	LIOTHYRONINE NA 25MCG TAB	CYTOMEL	Non-Formulary: no criteria for use	NON-FORMULARY
CN801	LISDEXAMFETAMINE ORAL CAP	VYVANSE	Non-Formulary: no criteria for use	NON-FORMULARY

AM900	LOMEFLOXACIN HCL ORAL	MAXAQUIN	Restricted to ID Service or local equivalent	NON-FORMULARY
CN709	LOXAPINE INJ	LOXITANE	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CN709	LOXAPINE ORAL SOLN 25MG/ML	LOXITANE	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
DE820	LST CREAM	LST CREAM	Non-Formulary: no criteria for use	NON-FORMULARY
GA900	LUBIPROSTONE ORAL CAPSULE	AMITIZA	Non-Formulary Criteria for Use of Lubiprostone VHA MAP/PBM-SHG Exclusions (if ONE is checked, patient is not eligible) - Treatment of constipation- or diarrhea-predominant irritable bowel syndrome (IBS) - Chronic constipation induced by medications that can be discontinued - History of or current symptoms of bowel obstruction - Presence of severe or frequent diarrhea - Women of child-bearing potential who have not had a baseline pregnancy test or in whom it has been determined that the potential risk to the fetus outweighs the benefit of therapy Indications For Therapy (all three criteria MUST be met) - Meets criteria for chronic functional constipation (refer to Diagnostic Criteria for	NON-FORMULARY

			Functional Constipation below) - Treatment of chronic constipation in patients who have documented lack of response or contraindication to, or inability to tolerate at least three agents on the VA National Formulary from the following drug classes (i.e., bulk-forming laxatives, osmotic laxatives, stimulant laxatives) as well as nonpharmacologic measures (e.g., adequate dietary changes, increased fluid intake, physical activity) - Evaluation of chronic functional constipation has been performed by appropriate personnel(1) Dosing - Recommended dose is 24 mcg twice daily orally with food Monitoring - Patients should be reevaluated after a 30 day trial. The patient should be encouraged to keep a daily report of stool frequency or other data deemed relevant by the prescriber, to assess the number of spontaneous bowel movements per week. Reassessment for efficacy by documenting symptom and/or quality of life improvement in the patient???s medical record is needed for continued use. - Monitor for severe or frequent diarrhea - Discuss risk vs. benefit of therapy in patients of child-bearing potential and appropriate methods of contraception Discontinuation - No documented constipation relief after 2 to 4 weeks of therapy (i.e., change in frequency, consistency or form of stool, bloating, discomfort or straining) (1) Refer for an appropriate gastrointestinal assessment if patient has symptoms or signs that suggest colorectal cancer or another serious gastrointestinal condition (refer to http://www.romecriteria.org/PDFs/p1480FBDs.pdf) Diagnostic Criteria* for Functional Constipation 1. Must include 2 or more of the following: - straining during at least 25% of defecations - lumpy or hard stools in at least 25% of defecations - sensation of incomplete evacuation for at least 25% of defecations - sensation of anorectal obstruction/blockage for at least 25% of defecations - manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor) - fewer than 3 defecations per week 2. Loose stools rarely present without the use of laxatives 3. There are insufficient criteria for IBS *Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis June 2007 VISN 20 P&T	
GU900	LUBRICANT MOISTURIZER VAGINAL GEL	REPLENS	Restricted to Women's Health providers or local facility equivalent.	NON-FORMULARY

HS702	LYPRESSIN NASAL INHL SOLN	DIAPID	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
HS900	MECASERMIN RINFABATE INJ	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
CN550	MECLIZINE HCL 25MG CHEW TAB	ANTIVERT	Non-Formulary: no criteria for use	NON-FORMULARY
IM100	MENINGOCOCCAL OLIGOSACCHARIDE DIPHTHERIA CONJUGATE VACCINE	MENVEO	NON-FORMULARY	NON-FORMULARY
IM100	MENINGOCOCCAL OLIGOSACCHARIDE DIPHTHERIA CRM197 CONJUGATE VACCINE	MENVEO	NON-FORMULARY	NON-FORMULARY
DE650	MENTHOL 10%/METHYL SALICYLATE 15% TOP OINT (OTC)	ANALGESIC OINT	Non-Formulary: no criteria for use	NON-FORMULARY
AM700	MENTHOL/METHYL SALICYLATE 16-30% (HIGH CONC) TOPICAL CREAM (OTC)	ANALGESIC CREAM	Open Formulary - no restrictions	NON-FORMULARY
CN400	MEPHENYTOIN ORAL	MESANTOIN	Non-Formulary: no criteria for use	NON-FORMULARY
XA103	MEPILEX ABSORBENT SILICONE DRESSING	MEPILEX	Non-Formulary: no criteria for use	NON-FORMULARY
X103	MEPILEX ABSORBENT SILICONE DRESSING	MEPILEX	Non-Formulary: no criteria for use	NON-FORMULARY
AM119	MEROPENEM IV	MERREM	Non-Formulary Criteria for Use: Meropenem September 2008 VHA Pharmacy Benefits Management Services and the Medical Advisory Panel FDA APPROVED INDICATION FOR USE Meropenem is indicated for the treatment of complicated skin and skin structure infections, intra-abdominal infections, and bacterial meningitis (pediatrics only) when caused by susceptible isolates of the designated microorganisms. EXCLUSION CRITERION O Known type I, immediate, or IgE-mediated hypersensitivity reactions to meropenem or other beta-lactams INCLUSION CRITERIA Meropenem may be used in place of imipenem for the following indications: O Patients in whom imipenem is otherwise indicated but who have	NON-FORMULARY

			one of the following risk factors that increase the likelihood of seizures while receiving imipenem - Patient with acute renal failure or undergoing continuous renal replacement therapy. - Patient with CNS disorder (e.g., history of seizure) or conditions that may lower the seizure threshold. - Concomitant administration of ganciclovir or valganciclovir O Nosocomial, post-operative or post-traumatic meningitis requiring empiric or pathogen-specific therapy that requires use of an anti-pseudomonal carbapenem. O Patient infected with multi-drug resistant Gram-Negative organism(s) that are resistant to imipenem and all other formulary beta-lactams but sensitive to meropenem. DOSAGE AND ADMINISTRATION (Refer to PI for dosage recommendations in organ dysfunction) Non-CNS infections: Meropenem 1gm intravenous infusion every 8 hours Bacterial meningitis: Meropenem 2gm intravenous infusion every 8 hours RECOMMENDED MONITORING Carbapenems, including meropenem, may reduce serum valproic acid concentrations to subtherapeutic values, resulting in loss of seizure control. Serum valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative antibacterial or anticonvulsant therapy should be considered if serum valproic acid concentrations drop below the therapeutic range or a seizure occurs. Similarly, patients treated with divalproex for bipolar disorders should be closely monitored and evaluated for dosage increase or alternative drug therapy. ISSUES FOR CONSIDERATION o Imipenem/cilastatin and ertapenem are formulary carbapenems. o Renal impairment: dosage should be reduced in patients with creatinine clearance less than 51 mL/min. o Although seizures and other CNS adverse experiences have also been reported during treatment with meropenem (particularly in patients with risk factors, e.g., CNS disorders, bacterial meningitis and/or renal impairment), the overall seizure risk is lower with meropenem than with imipenem. VISN 20 P&T Committee February 2009 .	
RS100	MESALAMINE ENEMA	ROWASA	Non-Formulary: no criteria for use	NON-FORMULARY
CN701	MESORIDAZINE BESYLATE INJ	SERENTIL	Non-Formulary: no criteria for use	NON-FORMULARY

CN701	MESORIDAZINE BESYLATE ORAL	SERENTIL	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
RE103	METAPROTERENOL SULFATE 20MG TAB	ALUPENT	Non-Formulary: no criteria for use	NON-FORMULARY
MS109	METFORMIN TAB,SA	FORTAMET	Non-Formulary: no criteria for use	NON-FORMULARY
CN101	METHADONE INJ 10MG/ML 1ML	DOLOPHINE	Non-Formulary: no criteria for use	NON-FORMULARY
AU100	METHOXAMINE HCL INJ	VASOXYL	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
GA900	METHYLNALTREXONE BROMIDE INJ	RELISTOR	Criteria for Nonformulary Use Methylnaltrexone Bromide Subcutaneous Injection March 2010 VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective	NON-FORMULARY

			drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services. A summary of the literature review used to support the criteria for nonformulary use of methylnaltrexone subcutaneous injection is available at http://www.pbm.va.gov or vaww.pbm.va.gov. FDA-approved Indication: Treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Use of methylnaltrexone subcutaneous injections beyond 4 months has not been studied. Exclusion Criteria If ANY item below applies, the patient should NOT receive methylnaltrexone subcutaneous injections. 0 Hypersensitivity to methylnaltrexone or product components 0 Known or suspected mechanical gastrointestinal obstruction or other condition that may compromise drug action or cause bowel dysfunction (e.g., acute abdomen, ostomy, active diverticulitis, ischemic bowel, postsurgical adhesions, rectocele, intussusception, active peritoneal cancer such as ovarian cancer) 0 Placement of peritoneal catheter for chemotherapy or dialysis (not studied) 0 End-stage renal impairment on dialysis (not studied) 0 Severe hepatic impairment / Child-Pugh grade C (not studied) 0 Pregnancy or nursing 0 Use of methylnaltrexone for prevention of opioid-induced constipation or impaction (no supporting evidence). 0 Use of methylnaltrexone for postoperative ileus (preliminary results showed inefficacy). 0 Use of methylnaltrexone for constipation that is not opioid-related (not studied) 0 Use of methylnaltrexone to treat opioid-induced constipation in patients not under hospice or palliative care Inclusion Criteria All of the following criteria must be met. 0 Prescriber is a palliative care specialist or provider locally designated to prescribe methylnaltrexone 0 Patient has advanced illness for which they are receiving palliative care in a monitored setting or at home with hospice care 0 Patient has opioid-induced constipation, requires PROMPT laxative effects, and has had an insufficient response, contraindication, unmanageable intolerance, or route of administration limitation (e.g., dysphagia) to a laxative regimen consisting of at least usual doses (see table below) of an oral and / or rectal stimulant laxative (e.g., bisacodyl,	

			sennoside), an oral and / or rectal stool softener (such as docusate), AND an oral osmotic laxative (such as lactulose or PEG 3350 in low doses). Opioid-induced constipation may be defined as either fewer than three bowel movements in the preceding week or no bowel movement for 2 days. Chronic daily stimulant-based laxative regimens should be continued and optimized in addition to using methylnaltrexone as needed. There is no evidence to support use of methylnaltrexone as monotherapy. Bulk laxatives are not recommended for opioid-induced constipation in palliative care patients because such patients are unlikely to maintain adequate hydration to prevent fecal impaction and bowel obstruction. VANF Palliative Care Laxative Regimens LAXATIVE FORMULATION INITIAL DOSE USUAL DOSE MAXIMUM DOSE (In divided doses, titrated to individual response) SENNOSIDES Oral tablet 15 mg once daily 15-50 mg once or twice daily 70 -100 mg in two divided doses OR BISACODYL Oral tablet 5 mg single dose 5-15 mg single dose 30 mg single dose Rectal suppository 10 mg single dose 10 mg single dose 10 mg single dose PLUS DOCUSATE Oral Capsule or Solution 50 mg once daily 50-360 mg in 1-4 divided doses 500 mg in 1-4 divided doses Rectal enema Add 50-100 mg of docusate liquid (not syrup) to enema fluid (saline or water) AND LACTULOSE Syrup 10 g (15 ml) once daily 10-20 g / day (15-30 ml / day) in 1-2 divided doses 60 ml / day in 1-2 divided doses OR PEG 3350 Powder for solution, oral 17 g (about 1 heaping Tbsp) of powder mixed in 4-8 oz of water, juice, cola, or tea once daily for not longer than 2 weeks Monitoring Patients who develop severe or persistent diarrhea after receiving methylnaltrexone should be monitored closely for dehydration. Dosing and Administration FOR SUBCUTANEOUS INJECTION ONLY Methylnaltrexone doses should be based on actual body weight and renal function as recommended in product information. Doses should be injected in the upper arm, abdomen, or thigh. Responders will typically have a bowel movement after at least one of the first three doses. Actual Body Weight Recommended Single Dose Injection Volume Dosing Frequency 38 to less than 62 kg (84 to less than 136 lb) 8 mg 0.4 ml The usual dosage regimen is one dose every 48 hours as needed (p.r.n.) Doses may be given at longer intervals as needed. If there is no laxation response after 7 d (3 doses), the patient is unlikely to respond to additional

			doses and methylnaltrexone should be discontinued. A maximum of 2 doses may be given 24 hours apart p.r.n. However, the need for dosing every 24 hours is exceptional, and the second dose should be given only if the previous day's dose is ineffective. Thereafter, resume dosing every 48 hours. 62 to 114 kg (136 to 251 lb) 12 mg 0.6 ml Outside of ranges shown above (Less than 38 kg or more than 114 kg) 0.15 mg / kg 0.0075 ml / kg (Round to nearest 0.1 ml) Severe Renal Impairment CrCl less than 30 ml / min Reduce dose by 50% End-stage renal impairment requiring dialysis: Not studied Mild or moderate hepatic impairment (Child-Pugh class A or B): No dosage adjustment necessary Severe hepatic impairment: Pharmacokinetics not studied Issues for Consideration The efficacy of methylnaltrexone was shown when it was added on to usual two- to three-drug laxative therapy. There is a lack of evidence to support treatment in patients other than those with advanced illness receiving palliative care. Duration of drug exposure in clinical trials and safety data are limited. Safety beyond 4 months of treatment has not been established; therefore, duration of treatment should be limited. Refills and Renewal Criteria 0 Limit of 3 doses and no refills for the initial prescription at recommended alternate-day dosing. 0 Documentation of patient benefit after at least one of the initial 3 doses given once every other day p.r.n. is required for subsequent refillable prescriptions. 0 Maximum duration of treatment is 4 months unless there is documentation of patient benefits, acceptable risks, AND need for continuing subcutaneous methylnaltrexone therapy (beyond 4 months) despite maximization of the patient's chronic stimulant-based laxative regimen. February 2010 VISN 20 P&T Committee	
CN105	METHYSERGIDE MALEATE ORAL	SANSERT	Non-Formulary: no criteria for use	NON-FORMULARY
NT900	MICONAZOLE BUCCAL TABLETS	ORAVIG	NON-FORMULARY	NON-FORMULARY
HS800	MICRONIZED PROGESTERONE ORAL	PROMETRIUM	Non-Formulary: no criteria for use	NON-FORMULARY
CN609	MILNACIPRAN	SAVELLA	NON-FORMULARY	NON-FORMULARY

MS300	MIVACURIUM INJ	MIVACRON	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

CN809	MODAFINIL ORAL	PROVIGIL	Sept 1999: Modafinil is non-formulary, a third-line treatment for sleepiness associated with narcolepsy, restricted to patients who are intolerant to or do not respond to current formulary alternatives dextroamphetamine and methylphenidate. March 2004 addition: VISN 20 Criteria for NF Use of Modafinil for MS-related fatigue 1. Prescribing authority limited to Neurology providers, or local facility equivalent. 2. Patient must have had an unsuccessful trial of amantadine due to either lack of efficacy at an adequate dose or development of intolerable adverse effects. Minimum therapeutic dose of amantadine for MS-related fatigue is 100 mg BID. 3. Other possible contributing factors of fatigue must be evaluated and controlled prior to treatment with modafinil. Possible contributing factors include depression, sleep disorders, and pain Initial treatment of choice for patients with depression and fatigue is a less sedating antidepressant such as Fluoxetine, sertraline, citalopram, nefazodone, or venlafaxine. Laboratory screening should also be performed to rule out other fatigue-producing conditions, such as thyroid function tests, complete blood cell count, measurement of electrolytes and glucose levels, and liver function tests. 4. Prior to initiation of modafinil, baseline efficacy measure should be determined. (FSS, MFIS, or VAS-F) 5. Initial dose should be 100 mg QAM. If the patient does not respond to a low dose, then the dose may be increased at increments of 100mg per day. Maximum dose is 400 mg/day, however studies have shown maximum efficacy at 200mg/day. Alternative dosing regimens include BID dosing such as 100mg BID, or 200mg BID. 6. Safety and efficacy should be evaluated throughout therapy and compared to baseline. 7. Modafinil should be discontinued if a therapeutic dose is not efficacious or if a patient suffers from adverse events. 8. Adequate trial should be determined by a neurology provider or local facility equivalent.	NON-FORMULARY
NT200	MOMETASONE 50 MCG NASAL INHALER	ELOCON, NASONEX	Non-formulary, nasal steroid for patients who are intolerant to, or have failed, flunisolide. The choice of preferred non-formulary nasal corticosteroid is determined locally depending on local site availability and current cost. VISN P&T March 2009	NON-FORMULARY
CN101	MORPHINE SO4 ORAL SUSTAINED RELEASE: ORAMORPH	ORAMORPH	Non-Formulary: no criteria for use	NON-FORMULARY
CN101	MORPHINE SO4 RECTAL SUPP	N/A	Non-Formulary: no criteria for use	NON-FORMULARY

CN101	MORPHINE-NALTREXONE	EMBEDA	NON-FORMULARY	NON-FORMULARY
IM100	MUMPS VIRUS VACCINE,LIVE	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AD100	NALTREXONE SA SUSP INJ	VIVITROL	Criteria for Nonformulary Use Naltrexone Extended-release Injectable Suspension VHA Pharmacy Benefits Management Services and the Medical Advisory Panel These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high-quality, cost-effective drug therapy. These criteria are not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations. Inclusion Criteria All of the following criteria must be met. 0 Naltrexone injectable will be initially prescribed by a VA or VA-contracted provider who has expertise in the treatment of alcohol dependence or is involved in the coordination of care with a VA or VA-contracted provider experienced in the treatment of alcohol dependence. 0 Patient is under the care of a VA physician for a current diagnosis of alcohol dependence (DSM-IV) 0 Patient is willing to receive monthly injections of medication for alcohol dependence 0 Patient is not taking illicit opioids or prescription opioid medications for at least 7 days 0 Patient is free of severe or active liver or kidney dysfunction (liver transaminases less than 5x ULN; bilirubin within normal limits [except in documented Gilbert's disease]; estimated or measured creatinine clearance 50 ml/min or greater) 0 Patient is engaged in a drug and alcohol treatment management program that includes psychosocial therapy (e.g., psychosocial interventions focused on relapse prevention, brief interventions / care management including assessment of treatment response) at initiation of injectable naltrexone therapy Individualize treatment plans. Generally, oral administration of drugs is preferred unless the patient is unwilling or unable to take oral medications. The patient's likely adherence with oral naltrexone should be considered, and prior nonadherence with other daily medications may justify use of injectable naltrexone. The injectable form may be particularly useful in patients who have difficulty adhering to an oral regimen or have not responded to motivational approaches. While documented abstinence is not required for therapeutic benefit with	NON-FORMULARY

			injectable naltrexone, even greater benefit may be seen in patients who achieve some duration of alcohol abstinence (e.g. 2-4 days) prior to the initial injection of naltrexone. Prior trials of oral naltrexone or other antialcoholic agents (e.g., acamprosate or disulfiram) are not required before injectable naltrexone; patients who have an inadequate response or intolerance to oral naltrexone may be given a trial of other agents (e.g., acamprosate or disulfiram) instead of injectable naltrexone, or they may be tried on injectable naltrexone. Routine use of naltrexone in combination with other antialcoholic medications is not recommended. Switching from oral naltrexone for alcohol dependence: There are no systematically collected data that specifically address the switch from oral naltrexone to naltrexone injection. Pretreatment with oral naltrexone is not required before using naltrexone injection. Exclusion Criteria 0 Patients who require opioid medications for therapeutic reasons. 0 Inadequate muscle mass. 0 Current physiologic opioid dependence or withdrawal. 0 Failed naloxone challenge or positive on urine drug screen for opioids, including methadone. 0 Hypersensitivity to any components of injectable naltrexone formulation. Criteria for Discontinuation 0 Patient develops clinically important increase in liver transaminases (e.g., 3 times baseline or 5 times the upper limit of normal), hepatitis, or hepatic failure. Naltrexone (injection or oral) should generally not be reinstituted. 0 Patient requires opioid therapy. Naltrexone injection may be reinstituted 7 or more days after discontinuation of opioid therapy. 0 Patient has NO beneficial response to intramuscular naltrexone within the first 3 consecutive months of therapy. If naltrexone injection must be discontinued, then the patient should be offered guideline-concordant drug therapy and other nondrug therapy for alcohol dependence. See the VA/DoD Clinical Practice Guideline on Substance Use Disorders at http://www.oqp.med.va.gov/cpg/cpg.htm . Although engagement in a management program that includes psychosocial therapy is an inclusion criterion for use, lack of engagement in such a program during therapy (e.g., in stable patients) should not be used as an exclusive criterion for discontinuation of naltrexone injection. Dosing and Administration Refer to the Product Information on injectable naltrexone for complete instructions on preparation and administration, available at:

			http://www.vivitrol.com/hcp/Default.aspx .. Inject 380 mg intramuscularly into the upper outer quadrant of a gluteal muscle, alternating buttocks, every 4 weeks or once a month. Renal Insufficiency. Mild renal insufficiency (creatinine clearance of 50-80 mL/min) had little or no influence on injectable naltrexone pharmacokinetics and no dosage adjustment is necessary. Injectable naltrexone pharmacokinetics have not been evaluated in subjects with moderate and severe renal insufficiency. These criteria recommend excluding patients with moderate to severe renal insufficiency from injectable naltrexone therapy. Prior to adding diluent to the vial of powdered drug, bring the drug to room temperature (about 45 minutes). The injection should be administered by a health care provider. Do not administer intravenously (i.v.) Patient Information Patients should be advised and providers should be aware that administration of large doses of opioids during naltrexone therapy may overcome the opioid-blocking effects of naltrexone and lead to serious injury, coma, or death. Patients will not perceive any effect if they take opioids in small doses while receiving naltrexone. Patients on naltrexone may not experience the same effects from opioid-containing analgesic, antidiarrheal, or antitussive medications. Patients should be advised that if they previously used opioids, they may be more sensitive to lower doses of opioids after naltrexone treatment is discontinued. Storage / Stability Store the entire dose pack in the refrigerator (20 to 80C; 360 to 460F). Do not freeze. Do not expose the product to temperatures above 250C (770F). Unrefrigerated, injectable naltrexone can be stored at room temperatures not exceeding 250C (770F) for no more than 7 days prior to administration. Prepared April 2008. Contact: Francine Goodman, Clinical Pharmacy Specialist, PBM Services VISN 20 P&T June 2008	
CN105	NARATRIPTAN ORAL TAB	AMERGE	ZOLMITRIPTAN is formulary, first line Sumatriptan and naratriptan are non-formulary, second line, reserved for patients who cannot be successfully treated with zolmitriptan. Sept 2001 Aug, Sept 2003	NON-FORMULARY
CV100	NEBIVOLOL ORAL TAB	BYSTOLIC	Non-Formulary: no criteria for use	NON-FORMULARY
CN609	NEFAZODONE ORAL	SERZONE	Non-Formulary: no criteria for use	NON-FORMULARY

TN404	NELARABINE	ARRANON	Nelarabine is non-formulary, restricted to Hematology/Oncology for patients with a history of at least 2 treatment failures and a diagnosis of either T-cell acute lymphoblastic leukemia or T-cell lymphoblastic lymphoma. March 2007 VISN 20 P&T Committee	NON-FORMULARY
HS200	NELOVA 0.5/35 28 DAY PACK	NELOVA	Non-Formulary: no criteria for use	NON-FORMULARY
OP300	NEPAFENAC OPHTHALMIC SUSPENSION	NEVANAC	Non-Formulary: no criteria for use	NON-FORMULARY
CV900	NESIRITIDE INJ	NATRECOR	The Non-Formulary use of Nesiritide is restricted as follows: 1. Use requires approval of a Staff Cardiologist or local facility equivalent. 2. Use is restricted to ICU patients. 3. Use is restricted to patients with decompensated heart failure, with a systolic blood pressure of 90 mmHg, who are volume overloaded, have congestive symptoms, are diuretic resistant (on high dose diuretics or with poor response to intravenous [IV] diuretics). 4. Use is limited to 48 hours. Contraindications: 1. Use is contraindicated in patients who are hypersensitive to any of its components. 2. Should not be used as primary therapy for patients with cardiogenic shock or in patients with a systolic blood pressure < 90 mmHg. Dosing & Duration of Therapy: Initial loading dose = an IV bolus of 2 mcg/kg, given IV bolus. Maintenance dose = a continuous IV infusion of 0.01 mcg/kg/minute. There is no dose titration. Duration of therapy should be 48 hours maximum. If goal diuresis is achieved prior to 48 hours, the infusion can be simply discontinued. There is no need to wean the infusion. Patient Monitoring: Nursing: Blood pressure, I&O. Medical: Baseline electrolytes, creatinine and BUN should be obtained. Nesiritide can cause a brisk diuresis and electrolytes should be monitored and replaced appropriately. The administration of nesiritide does not require telemetry monitoring.	NON-FORMULARY
VT103	NIACIN ORAL, 100MG, 500MG IR TAB (OTC)	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AD900	NICOTINE NASAL SPRAY	NICOTROL	Nicotine nasal spray (Nicotrol) is non-formulary, restricted to smoking cessation clinics or local facility equivalent ONLY for treatment of breakthrough cravings as second-line therapy after failure or intolerance to nicotine polacrilex gum, and limited to a maximum dosage of 5 mg/day (5 doses/day) and maximum duration of three months therapy.	NON-FORMULARY
CV200	NIFEDIPINE IMMEDIATE RELEASE ORAL	PROCARDIA	Restricted to VHS National Criteria for non-formulary use, which are: restricted to spinal cord injury patients	NON-FORMULARY

			to treat hypertension due to autonomic dysreflexia, patients with hypertensive urgency prior to anesthesia induction in the operating room, and patients with vasospastic angina in the cath lab. (September 2004 VISN 20 P&T Committee) January 1999 VISN 20 Formulary Committee: Available on a Non-Formulary basis for patients who fail the Autonomic Dysreflexia (AD) protocol. AUTONOMIC DYSREFLEXIA (AD) PROTOCOL - Northwest Network IF SIGNS OR SYMPTOMS OF AD ARE PRESENT: 1. Sit patient upright. 2. If an external blood pressure monitor was used, recheck to confirm blood pressure with a manual BP cuff. Recheck blood pressure every 5 minutes. 3. If bladder catheter is in place, check for kinking. 4. If catheter is plugged, attempt to clear by gentle irrigation. 5. If needed, change the catheter using lidocaine jelly as the lubricant. Drain the bladder. 6. If no catheter is present, insert one using lidocaine jelly for lubrication. Drain the bladder. 7. Loosen clothing, abdominal binder, leg wraps. 8. Check skin for any noxious stimulus and remove/relieve; wrinkle in covers, tight jeans, objects poking against the skin. 9. Lubricate gloved finger with lidocaine jelly, insert and apply to anal sphincter, wait three minutes. 10. Check rectum for stool. If present, manually disimpact with gloved finger lubricated with lidocaine. IF PATIENT IS STILL SYMPTOMATIC, AND/OR REACHES 160 SBP OR 100 DBP: 1. Apply one inch of nitroglycerin paste on hairless skin, cover with plastic wrap. 2. If blood pressure has not responded after 10 minutes, apply an additional inch of nitroglycerin paste, for a total of two inches. Cover with plastic wrap. 3. If no response after another 10 minutes, give patient 10 mg of oral hydralazine. 4. If no response after an additional 20 minutes, give patient an additional 10 mg of hydralazine. 5. Call the physician STAT if SBP reaches 180/110, or if BP does not respond to the initial application of nitroglycerin paste. Call physician STAT if symptoms resolve and the SBP falls below 80. 6. Order STAT 12 lead EKG. 7. Start IV line and begin D5 half normal saline to keep open. 8. Wipe nitroglycerin paste off when SBP comes down to 130. 9. Continue to check BP every 15 minutes for one hour, then every hour for subsequent 4 hours. Short-acting nifedipine is now non-formulary, and should be reserved only for patients that are refractory to the above measures. In light of the FDA guidelines specifying a moratorium on the use of short-acting nifedipine in hypertensive emergencies	

			due to life-threatening sequelae, review of the literature, and the recent adverse drug reaction resulting in cardiac ischemia in the Seattle SCI unit, its use is strongly discouraged.	
AN900	NILOTINIB	TASIGNA	NON-FORMULARY	NON-FORMULARY
AN900	NILOTINIB	TASIGNA	NON-FORMULARY	NON-FORMULARY
CV200	NIMODIPINE 30MG CAP	NIMOTOP	Restricted to Neurology Service or local equivalent.	NON-FORMULARY
AM600	NITROFURANTOIN MACROCRYSTAL ORAL	MACRODANTIN	Non-Formulary: no criteria for use	NON-FORMULARY
CN201	NITROUS OXIDE	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
HS200	NORELGESTROMIN/ETHINYL ESTRADIOL PATCH	ORTHO EVRA	Non-Formulary: no criteria for use	NON-FORMULARY
TN200	NUTRITION SUPL OSMOLITE HN LIQUID (OTC)	OSMOLITE	VISN 20 OUTPATIENT NUTRITIONAL SUPPLEMENT POLICY - July 7, 2005 DEFINITION: A nutritional supplement is defined as a commercially prepared product designed to be consumed in the place of food or in addition to foods. POLICY: A. Nutritional supplements that can be taken orally will not be prescribed for outpatient veterans. High risk patients should be referred to the Registered Dietitian (RD) (Attachment B) for instruction on appropriate diet intervention and/or food/supplement items available locally. B. Patients who indicate financial hardship may be referred to Social Work Services for information and referral to available community resources. C. The provision of enteral nutritional supplements for outpatients is limited to: (1) Patients receiving tube feeding. (2) Prescriptions for enteral nutritional supplements are limited to 12 months. Each new prescription or renewal for enteral nutritional supplements requires the completion of a new Enteral Nutritonal Supplement Recommendation Form. D. Criteria for receiving nutritional supplements also apply to fee basis patients. PROCEDURE: A. Non-tube feeding (oral) patients with a recent albumin less than 3, current BMI	NON-FORMULARY
HS900	OCTOXYNOL 9 SPERMICIDAL JELLY 3.8OZ	ORTHO-GYNOL	Non-Formulary: no criteria for use	NON-FORMULARY
AN900	OFATUMUMAB	ARZERRA	NON-FORMULARY, CFU	NON-FORMULARY
AM900	OFLOXACIN INJ	FLOXIN	Restrictions per local facility	NON-FORMULARY
AM900	OFLOXACIN ORAL	FLOXIN	Non-Formulary: no criteria for use	NON-FORMULARY
CN709	OLANZAPINE PAMOATE	ZYPREXA RELPREVV	NON-FORMULARY	NON-FORMULARY

OP900	OLOPATADINE OPHTHALMIC SOLN	PATANOL	Non-Formulary: no criteria for use	NON-FORMULARY
IM600	OMALIZUMAB	XOLAIR	Revised VA National Omalizumab Non-Formulary Criteria for Use Exclusion - Prior allergic reaction to omalizumab - Do not use to treat acute exacerbation of asthma or status asthmaticus Inclusions The following 8 criteria must be met: - Patient has moderate-severe persistent asthma - Provider is a pulmonologist or allergy specialist - Patient is symptomatic despite having received optimal therapy for their asthma (e.g., medium-high dose inhaled corticosteroid and long-acting beta2-agonist). - Patient is compliant with their medications as evidenced by a review of compliance with refilling prescriptions during the last 12 months. - Patient should be nonsmoking and if not, actively receiving smoking cessation treatment2 - Pre-treatment serum IgE 30-700 IU/ml - Positive skin tests or in vitro reactivity to common aeroallergen (e.g. dust mites, pet dander, and cockroach). - Patient has an epinephrine pen AND at least 1 of the following: - Repeated use of health care services (urgent clinic visit, ER visit, urgent phone call management, or hospitalization) in the last 12 months due to asthma OR - Oral steroid dependent (must have documentation that previous attempts at dosage reduction or discontinuation lead to exacerbation) November 2007 VISN 20 P&T Committee	NON-FORMULARY
TN900	OMEGA-3 FATTY ACIDS 1200MG CAP	PROMEGA	Omega-3 Fatty Acid Products are restricted to patients with hypertriglyceridemia when niacin or gemfibrozil is contraindicated or not tolerated, or when a single lipid-lowering agent is inadequate in decreasing triglycerides. VISN 20 P&T Committee February 2010	NON-FORMULARY
GA400	OPIUM 10% TINCTURE	DEODORIZED OPIUM TINCTURE	Restricted to patients unable to take paregoric or morphine equivalent	NON-FORMULARY
GA900	ORLISTAT	XENICAL	Orlistat (Xenical) Non-Formulary Criteria for Use Orlistat is approved for the management of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a calorie deficit diet. Patients who meet or continue to meet the criteria-for-use and whose prescriber has completed a non-formulary request form can be dispensed orlistat. Criteria-for-Use for Initial 90 Day Supply The patient is enrolled in a MOVE program or similar VA multidisciplinary weight loss program The patient has demonstrated the ability to comply with a low-fat diet The patient's BMI is: Greater than or equal to 30 kg/m2 OR Greater than or equal to 27 kg/m2 with the	NON-FORMULARY

			presence of other co-morbid conditions affected by being over weight or obese such as controlled hypertension, diabetes, and dyslipidemia. The patient has no contraindications to orlistat including hypersensitivity and with chronic malabsorption syndrome or cholestasis. The patient is taking or receives a prescription for a multivitamin Patients who fail to meet all these criteria are ineligible for treatment with orlistat. ---------- Criteria for Initial 90 Day Refill The patient has attended follow-up appointments. Initial follow-up is to be in 2 to 4 weeks after starting orlistat, then monthly for 3 months. The patient is to be weighed at each follow-up visit. After 12 weeks, the patient has lost at least 5% of their body weight or an average of >1 lb. per week. The patient is not experiencing intolerable side effects. The patient wishes to continue orlistat. The patient has no contraindications to orlistat including hypersensitivity and with chronic malabsorption syndrome or cholestasis. Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued. ---------- Criteria for Refills every 6 months The patient has maintained 67% of their initial weight loss to date or has continued to lose weight. The patient has attended follow-up visits every 3 months. The patient is not experiencing intolerable side effects. The patient wishes to continue orlistat. The patient has no contraindications to orlistat including hypersensitivity and with chronic malabsorption syndrome or cholestasis. The patient has been taking orlistat for less than 4 years. Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued. Four years is the maximum duration of treatment. ========== Full criteria MAY be found at: http://vaww.pbm.va.gov/criteria/39t5uOrlistat%20CFU.pdf October 21, 2005 VISN 20 P&T Committee	

HS100	OXANDROLONE ORAL	OXANDRIN	Oxandrolone is non-formulary, restricted to the following criteria (a specific Northwest Network oxandrolone request form was developed by Puget Sound): 1. Restricted to use in spinal cord injury patients, prescribed by SCI attending or local facility equivalent. 2. Patients must have a documented non-healing pressure ulcer with no change in healing while receiving adequate nutritional support (high calorie and high protein diet) for the previous eight weeks. 3. Patients must have nutritional compromise demonstrated by albumin < 3.4 4. Patients must have nutritional compromise demonstrated by > 10% loss of body weight in the previous six months. 5. L-glutamine packets (one packet per day) will be used with oxandrolone for the first month of treatment only. 6. Oxandrolone therapy is limited to 12 weeks. May 2007	NON-FORMULARY
CN302	OXAZEPAM ORAL	SERAX	Non-Formulary: no criteria for use	NON-FORMULARY
CN400	OXCARBAZEPINE ORAL	TRILEPTAL	Nov 2001, Mar 2004: (1) Oxcarbazepine (Trileptal) is non-formulary, restricted to Neurology Service or local facility equivalent use/approval for patients who fail, have contraindications to, or who develop intolerable side effects to traditional formulary antiepileptics. (2) Currently, oxcarbazepine is FDA approved for monotherapy or adjunctive therapy in the treatment of partial seizure in adults with epilepsy and as adjunctive therapy in the treatment of partial seizures in children aged 4-16 with epilepsy. Non-formulary requests for the use of oxcarbazepine for indications that are not currently approved by the FDA, such as pain or neuropathies, should not be approved until clinical studies are conducted to demonstrate its safety and efficacy for these indications. Feb 2004: Specific criteria for Bipolar disorder: (1) Patients responding to carbamazepine who are experiencing side effects/drug interactions may be treated with oxcarbazepine if have previously failed therapy with lithium, valproate, and combination therapy. (2) Prescribers should be aware that not all side effects/drug-drug interactions are seen less with oxcarbazepine than with carbamazepine.	NON-FORMULARY
IR100	OXYCHLOROSENE	CLORPACTIN	Non-Formulary: no criteria for use	NON-FORMULARY
CN101	OXYCODONE,SUSTAINED RELEASE TAB (OXYCONTIN)	OXYCONTIN	Sustained release oxycodone is available by non-formulary drug request for patients with severe terminal pain who have contraindications to or do not respond to other oral therapies and transdermal fentanyl. May 1998, August 2007	NON-FORMULARY

CN101	OXYMORPHONE ORAL TABLETS	NUMORPHAN	Non-Formulary Criteria for Use of Oxymorphone Oral Tablets Inclusion Criteria for Use: Patient must meet all of the following criteria to use Oxymorphone Oral Tablets. 1 Patient has moderate to severe pain. 2 Patient is able to take oral solid medications (intact tablets). 3 Patient has had documented intolerable adverse effects to ALL of the opioids listed below (according to oxymorphone formulation), and the adverse effects persisted despite aggressive measures to alleviate them and prevented upward titration of dosage to achieve a satisfactory level of analgesia. o Before trying immediate release of oxymorphone tablet, patient must tries hydrocodone/acetaminophen, morphine, oxycodone, and hydromorphone. o Before trying extended release of oxymorphone tablet, patient must tries morphine, methadone (see exception*), oxycodone. *Methadone should ideally be initiated by or in consultation with a practitioner who has knowledge in titration of this agent. In situations where there is no practitioner or consultant with experience in using methadone for chronic pain, another long-duration opioid may be used until such consultation can be obtained. Also refer to Methadone Dosing Recommendations for Treatment of Chronic Pain available at http://www.pbm.va.gov. 4 Patient is under the care of a pain management specialist. It is recommended that providers ask patients to review and sign an Opioid Agreement. Providers should also advise patients to take oxymorphone tablets consistently on an empty stomach, avoid alcohol consumption during therapy with oxymorphone tablets, and inform their provider if they are unable to adhere to these precautions. Exclusions: Patient should not receive Oxymorphone if any of the following criteria are met (applicable to both immediate- and extended-release tablets). 1 Patient has mild pain. 2 Patient has decreased consciousness or gastrointestinal obstruction. 3 Patient has a documented or suspected contraindication (e.g., drug hypersensitivity) to the use of oxymorphone or morphine analogs, or contraindication to other opioids (e.g., significant respiratory depression (without resuscitative equipment or careful medical monitoring), acute or severe bronchial asthma or hypercarbia, or known or suspected paralytic ileus). 4 Patient has moderate or severe hepatic impairment. Exclusions: (applicable to immediate-release tablets) 1 Initial dose is more than 20mg in patients considered to be opioid naive (single	NON-FORMULARY

			doses of 30mg did not provide additional benefit over 20mg and were associated with a higher incidence of nalaxone use postoperatively). Exclusions: (applicable to extended-release tablets) 1 Patient requires tablets to be broken, chewed, crushed, or dissolved before administration. 2 Patient is not expected to have pain for an extended period of time (e.g., more than several days). 3 Patient is not previously taking the drug and requires rapid onset of analgesia for pain in the immediate post-operative period (first 12 to 24 hours after surgery) or does not have moderate to severe postoperative pain that is expected to persist for an extended period of time. 4 Patient only requires rapid onset of analgesia, such as in the treatment of acute pain, incident pain (episodic increases in chronic pain intensity that may or may not be related to movement or activity), or breakthrough pain (chronic pain that is inadequately treated). 5 Patient only requires an as-needed (P.R.N.) analgesic. 6 Co-ingestion of alcohol, including alcohol contained in nonprescription or prescription medications (Alcohol may increase oxymorphone plasma levels and the risk of potentially fatal toxicity). January 2007	
AM900	PALIPERIDONE ORAL TAB	INVEGA	Non-Formulary: no criteria for use	NON-FORMULARY
AN900	PANITUMUMAB INJ	VECTIBIX	Panitumumab is non-formulary, restricted to Hematology/Oncology or local facility equivalent for salvage therapy for patients with metastatic colorectal cancer who progress on current standard of care regimens comprised of a fluoropyrimidine, oxaliplatin, and/or irinotecan containing chemotherapy regime. April 2007	NON-FORMULARY

GA900	PANTOPRAZOLE INJ	PROTONIX	IV Pantoprazole - National & VISN 20 VA Criteria for Use 1. Patient must be NPO AND 2. ONE OF THE FOLLOWING CONDITIONS MUST BE MET: a. Clinical signs of significant upper gastrointestinal bleeding before urgent endoscopy in patients with high risk for peptic ulcers b. Confirmed active or recent peptic ulcer bleeding associated with endoscopic stigmata suggestive of high risk for re-bleeding (active acute hemorrhage, nonbleeding visible vessel (NBVV), or lesion with sentinel clot) c. Bleeding or severe erosive esophagitis d. Pathologic hypersecretion associated with Zollinger-Ellison syndrome e. Contraindication to using histamine2-receptor antagonists (H2RAs) (e.g., H2RA-related thrombocytopenia) for stress ulcer prophylaxis (SUP). Inappropriate Indications for Use: 1. Patient is not NPO 2. Stress Ulcer Prophylaxis 3. Temporary conversion of an oral PPI in a patient who is made NPO, but who does not have an upper GI bleed or a contraindication to H2RAs (IV H2RAs should be used). September 2006 VISN 20 P&T Committee	NON-FORMULARY
GA900	PANTOPRAZOLE NA 40MG EC TAB	PROTONIX	If a patient receiving clopidogrel requires treatment with a PPI, requests for the concomitant use of the non-formulary agent, pantoprazole, may be accepted. March 2009 VISN 20 P&T Committee	NON-FORMULARY
CV500	PAPAVERINE INJ 30MG/ML 10ML	PAVATINE	Non-Formulary: no criteria for use	NON-FORMULARY
VT502	PARACALCITOL INJ	ZEMPLAR	Paricalcitol is non-formulary, but available on a non-formulary basis for renal dialysis patients failing calcitriol therapy or intolerant to calcitriol. Acceptable evidence for failure to calcitriol would be inability to reach the therapeutic end points of therapy at maximum calcitriol dose or onset of severe adverse effects such as hyperphosphatemia or hypercalcemia. Intact PTH levels should be followed to monitor efficacy	NON-FORMULARY
GU900	PARAGARD INTRAUTERINE DEVICE (I.U.D.)	PARAGARD T CU380A	Not provided by VA Pharmacy Service.	NON-FORMULARY
VT502	PARICALCITOL INJ	ZEMPLAR	Paricalcitol is non-formulary, but available on a non-formulary basis for renal dialysis patients failing calcitriol therapy or intolerant to calcitriol. Acceptable evidence for failure to calcitriol would be inability to reach the therapeutic end points of therapy at maximum calcitriol dose or onset of severe adverse effects such as hyperphosphatemia or hypercalcemia. Intact PTH levels should be followed to monitor efficacy	NON-FORMULARY
AN900	PAZOPANIB	VOTRIENT	NON-FORMULARY	NON-FORMULARY

AN900	PEGAPTINIB OCTASODIUM INJ	MACUGEN	Pegaptanib Sodium is non-formulary, restricted to the VA National Non-Formulary Criteria for Use: Inclusion Criteria: Diagnosis of subfoveal choroidal neovascularization (CNV) secondary to Age Related Macular Degeneration (AMD); Lesion subtype of predominately classic, minimally classic or occult; Total lesion size up to 12 disc areas including blood, scar, atrophy, or neovascularization; Best corrected Visual Acuity (VA) 20/40 to ability to count fingers; Subretinal hemorrhage constituting 50 years. Exclusion Criteria: CNV due to conditions other than AMD; Scarring or atrophy constituting >25% of total lesion size; Previous subfoveal thermal laser photocoagulation; Hypersensitivity to pegaptanib; or Current evidence of endophthalmitis or elevated intraocular pressure (IOP). Dose and duration: Pegaptanib is administered as 0.3 mg every six weeks by intravitreous injection using aseptic technique. This includes the use of sterile gloves, sterile drape and sterile eyelid speculum. Anesthesia and a broad spectrum antibiotic should be administered to the eye to be treated. Following injection, patients should be evaluated for evidence of IOP. Patients should be educated on the signs/symptoms of endophthalmitis. Currently available evidence supports the use of pegaptanib over a nine injection time frame (54 weeks). Therapy past this time should be evaluated on a case by case basis. August 19th, 2005	NON-FORMULARY
BL400	PEGFILGRASTIM 10MG/ML INJ	NEULASTA	Pegfilgrastim (Neulasta) is non-formulary, restricted to patients receiving myelosuppressive chemotherapy. Its use is restricted to (1) patients who are unable to self-inject filgrastim and would require a home-health nurse or other practitioner to administer growth factor injections or (2) when pegfilgrastim provides a cost-efficient alternative to daily filgrastim injections Jan 2003, Feb 2005 VISN 20 P&T Committee Minutes	NON-FORMULARY

AN300	PEMETREXED INJ	ALIMTA	Pemetrexed (Alimta) is non-formulary, restricted to the following national criteria: (1) patients with mesothelioma: unresectable disease without brain metastases, good performance status (e.g., ECOG PS 0-2), adequate renal function (creatinine clearance >45ml/min), not taking NSAIDs, able to comply with the vitamin supplementation regimen* (2) patients with non-small-cell lung cancer: Stage IIIB or IV NSCLC without brain metastases, one prior chemotherapy regimen, adequate renal function (creatinine clearance > 45ml/min), not taking NSAIDs, no pleural effusion or third-spacing of fluid, good performance status (e.g., ECOG PS 0-2), able to comply with the vitamin supplementation regimen*. *Vitamin supplementation regimen: Folic Acid 350-1,000 mcg (the most common dose in clinical trials = 400 mcg) at least 5 daily doses during the 7-days preceding the first dose of pemetrexed, then daily during therapy and for 21 days after the last dose of pemetrexed. Vitamin B12 (cyanocobalamin) 1,000mcg intramuscularly during the week before the first dose of pemetrexed and then every 3 cycles (every 9 weeks) thereafter. Dose may be administered on the same day as pemetrexed after the first dose. April 2005	NON-FORMULARY
DX900	PENTAGASTRIN INJ	PEPTAVLON	Non-Formulary: no criteria for use	NON-FORMULARY
CN301	PENTOBARBITAL INJ 50MG/ML 50ML	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
GU900	PENTOSAN POLYSUFLATE SODIUM ORAL CAP	ELMIRON	Pentosan polysulfate sodium (Elmiron) is non-formulary, restricted to Urology Service or local facility equivalent for limited use in patients with interstitial cystitis refractory to treatment with intravesicular DMSO. VISN 20 P&T May 2007	NON-FORMULARY
CV900	PENTOXIFYLLINE	TRENTAL	Non-Formulary: no criteria for use	NON-FORMULARY
GA400	PEPTO-BISMOL ORAL SUSPENSION	PEPTO-BISMOL	Non-Formulary: no criteria for use	NON-FORMULARY
CN500	PERGOLIDE MESYLATE ORAL TAB	PERMAX	Non-Formulary: no criteria for use	NON-FORMULARY

CN701	PERPHENAZINE INJ	TRILAFON	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CN701	PERPHENAZINE ORAL SOLN 16MG/5ML	TRILAFON	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CV100	PINDOLOL 5MG, 10MG TAB	VISKEN	Non-Formulary: no criteria for use	NON-FORMULARY
HS502	PIOGLITAZONE	ACTOS	Criteria for Non-formulary Use of Thiazolidinediones VHA Pharmacy Benefits Management Service and the Medical Advisory Panel Pioglitazone is the agent of choice for patients newly starting on a thiazolidinedione (TZD). For patients currently receiving rosiglitazone the decision to continue rosiglitazone should be made in light of the available data only after a discussion of the risks and benefits of this and alternate therapies with the patients. Exclusions (if ONE is selected, patient is not eligible) - Type 1 Diabetes Mellitus - Pre-diabetes: impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)1 - New York Heart Association (NYHA) Class III or IV heart failure - Evidence of active liver disease or an ALT > 2.5 x the upper limit of normal -	NON-FORMULARY

			Developed significant heart failure while taking another thiazolidinedione (TZD) - Experienced jaundice while taking another TZD Inclusions for patients with Type 2 diabetes The following must be acknowledged before proceeding - Fluid status must be monitored for all patients; however, extra vigilance is required for patients with NYHA Class I/II heart failure or patients with risk factors for heart failure and/or when combining a TZD with insulin. Both TZDs carry a Black Box Warning that use is not recommended in symptomatic heart failure. Use as monotherapy (both must be selected) - Is intolerant of or has contraindications to both sulfonylureas and metformin - Target value for HbA1c based on VA/DoD Guidelines http://www.oqp.med.va.gov/cpg/DM_base.htm is likely to be attainable based on clinical trial data Insulin may be considered at anytime prior to using a TZD; however, it should be considered if patient is symptomatic or a greater reduction beyond what is achievable by TZDs is desired. In the pivotal trials the AVERAGE decrease in HbA1c ranged from 0.6-0.8%. The mean decrease was greater in those with higher baseline HbA1c (e.g 2.5% in those with baseline HbA1c of 10%) Combination (2 drug) oral therapy - Target value for HbA1c based on VA/DoD Guidelines http://www.oqp.med.va.gov/cpg/DM_base.htm is likely to be attainable based on clinical trial data AND one of the following - Inadequate glycemic control on monotherapy with a sulfonylurea (at > 50% maximal dose or highest tolerated dose) AND is intolerant of or has contraindications to metformin - Inadequate glycemic control on monotherapy with metformin (at > 2g/d or highest tolerated dose) AND is intolerant of or has contraindications to sulfonylureas Insulin may be considered at anytime prior to using a TZD; however, it should be considered if patient is symptomatic or a greater reduction beyond what is achievable by TZDs is desired. In the pivotal clinical trials the AVERAGE decrease in Hba1c ranged from 0.5 -1.6% for the combination of a SU +TZD and 0.6-1.0% for metformin + TZD Triple oral therapy (all 3 must be selected) - Inadequate glycemic control on 2-drug therapy with a sulfonylurea (at > 50% maximal dose or highest tolerated dose) and metformin (at > 2g/d or highest tolerated dose) - Patient is not a good candidate for or refuses addition of insulin - Target value for HbA1c based on VA/DoD Guidelines http://www.oqp.med.va.gov/cpg/DM_base.htm is likely	

			to be attainable based on clinical trial data In the triple oral therapy trials, the AVERAGE decrease in HbA1c ranged from 0.4 - 1.9% TZD + insulin - Evidence of insulin resistance (e.g. acanthosis nigricans, polycystic ovary disease, total insulin dose > 1 unit/kg/day or > 100 units/day - these doses are considered as guidance and are not intended as absolute) and not at target HbA1c goal OR - Inadequate glycemic control with insulin therapy (e.g. due to hypoglycemia, patient refusing intensification of insulin regimen) Consider use of metformin prior to a TZD unless contraindicated The dose of rosiglitazone when combined with insulin should not exceed 4mg daily. The dose of pioglitazone should begin at 15 or 30 mg once daily and titrated according to glucose response. In the clinical trials, where a TZD was added to insulin, the AVERAGE decrease in HbA1 ranged from 0.6 to 1.5%. In one study, HbA1c decreased by > 0.7% in 27% of patients. The mean decrease in insulin dose was 23% (32% had at least a 30% decrease in insulin dose) Renewal Criteria A significant minority of patients do not have a response to TZDs; therefore, to continue use, meaningful improvement in glycemic control after 3-6 months of therapy in the absence of significant adverse events must be demonstrated. In the case of TZD + insulin in patients with significant insulin resistance, a meaningful decrease in insulin dose and/or improvement in glycemic control must be demonstrated. notes The use of TZDs to prevent the development of diabetes in this population is not recommended. Although rosiglitazone had recently been shown to reduce the frequency of diabetes in individuals with IFG/IGT, the incidence of adverse cardiovascular events (secondary outcome) was higher in those receiving rosiglitazone. Lifestyle interventions (diet and exercise), which have also been shown to be effective, should be emphasized and initiated first. If patient is near their glycemic goal (e.g.	
CN701	PIPERACETAZINE ORAL	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
XX000	PLACEBO ORAL	N/A	Non-Formulary: no criteria for use	NON-FORMULARY

AN200	PLICAMYCIN INJ	MITHRACIN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
DE500	PODOFILOX 0.5% GEL	CONDYLOX	Non-Formulary: no criteria for use	NON-FORMULARY
PH000	PODOPHYLLIN PWDR	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AM700	POSACONAZOLE ORAL SUSPENSION	NOXAFIL	Posaconazole is non-formulary, restricted to ID and Transplant providers or local facility equivalent. March 2007 VISN 20 P&T Committee	NON-FORMULARY
PH000	POTASSIUM PERMANGANATE GRANULES	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
CN500	PRAMIPEXOLE ORAL	MIRAPEX	Pramipexole (Mirapex) tablets are non-formulary, restricted to Neurology and Geriatric Services or local facility equivalent as second-line after ropinirole for the treatment of Parkinson's disease and third-line for the treatment of restless leg syndrome (RLS) in patients who have not responded or are intolerant to carbidopa/ levodopa and ropinirole. February 2008 VISN 20 P&T Committee	NON-FORMULARY
HS503	PRAMLINTIDE INJ	SYMLIN	Pramlintide (Symlin) Non-Formulary Criteria for Use Inclusion criteria (all inclusion criteria must be met) O The prescriber specializes in diabetes management O Patient is on insulin therapy O Documentation that patient has not achieved desired HbA1c despite multiple titration and adjustments with various basal/bolus insulin dosing regimens (including the use of insulin analogs) O Patient is willing to accept 2-3 injections/day of pramlintide in addition to that of insulin O Patient has demonstrated proficiency and compliance of SMBG and is willing to perform self-monitoring of blood glucose pre- and postprandially and at bedtime (until stabilized on dose) Exclusion criteria: O Patient has a HbA1c > 9% O Patient experiences frequent or severe hypoglycemia* O Patient has	NON-FORMULARY

			hypoglycemia unawareness O Patient has a confirmed diagnosis of gastroparesis O Patient is taking drugs known to alter GI motility (e.g. GI anticholinergics, metoclopramide, tegaserod) O Patient is using an ??-glucosidase inhibitor (acarbose, miglitol) O Patient is with creatinine clearance < 50 mL/min * Pramlintide carries a black box warning for insulin-induced severe hypoglycemia. Hypoglycemic risk in higher in patients with type 1 diabetes, and usually occurs within 3 hours of injection. Patient and/or caregiver must be educated on the following: O Patient and/or caregiver must be taught not to confuse insulin and pramlintide O Do not mix pramlintide and insulin in the same syringe. Use a separate syringe and needle for pramlintide O Pramlintide must be injected into a site that is different from where insulin is injected. Injection sites should be rotated O Patient and/or caregiver must be able to demonstrate how do draw up a dose of pramlintide using an insulin syringe (see caution box on page 2) O Pramlintide is injected into abdomen or thigh immediately prior to each major meal containing >250kcal or > 30gm of carbohydrate O If a dose of pramlintide is missed, an additional injection should not be given O Patient should be warned for the potential for hypoglycemia and signs and symptoms of hypoglycemia be reiterated Cautions: Presently, the manufacturer recommends using a U-100 insulin syringe for administering pramlintide. As a result, there is significant concern regarding the potential for errors in dosing pramlintide. O There is a risk that users may confuse micrograms with units. For example, 30 mcg (5 units on an insulin syringe) could be mistaken for 30 units, leading to a 6-fold overdose of pramlintide. O For prescriptions, the dose of pramlintide must be written in micrograms. Do not express the dose in insulin syringe equivalents. For example, the dose of pramlintide should be written as 120mcg not as 20 units. O If a tuberculin syringe was to be substituted for the U-100 syringe, there may be confusion because the conversion table in the patient information leaflet does not contain the volumetric measure (3rd column on conversion table below) Conversion of pramlintide dose to insulin unit equivalents Pramlintide dose (mcg) Increment using a U-100 syringe (units) Volume (mL) 15 2.5 0.025 30 5.0 0.05 45 7.5 0.075 60 10 0.1 120 20 0.2 From pramlintide product package insert O Thiazolidinediones (rosiglitazone, pioglitazone) have not been studied in combination with pramlintide:	

			concurrent use should be avoided. Dosing Dosing for type 2 diabetes: O Initial dose is 60mcg given subcutaneously immediately prior to major meals (> 250kcal or containing > 30 g of carbohydrate). O Reduce the dose of preprandial rapid-acting or short-acting insulin (including premixed 70/30 or 75/25 preparations) by 50% O If no clinically significant nausea has occurred for 3-7 days, increase the dose to 120mcg prior to major meals. If the 120mcg dose is not tolerated due to nausea, reduce the dose to 60mcg O Once a stable dose of pramlintide has been reached (nausea subsided), the dose of insulin may be adjusted to optimize glycemic control, as directed by a healthcare practitioner Dosing for type 1 diabetes: O Initial dose 15mcg subcutaneously immediately prior to major meals (>250kcal or containing > 30 g of carbohydrate). O Reduce the dose of preprandial rapid-acting or short-acting insulin (including premixed 70/30 or 75/25 preparations) by 50% O The dose is titrated in 15mcg increments to 30, 45, or 60mcg. If no clinically significant nausea has occurred for at least 3 days, increase the dose to the next increment. If the 30mcg dose is not tolerated, consider discontinuing pramlintide O Once a stable dose of pramlintide has been reached (nausea subsided), the dose of insulin may be adjusted to optimize glycemic control, as directed by a healthcare practitioner *Concomitantly administered oral agents that require rapid onset (e.g. analgesics) should be taken at least 1 hour prior to or 2 hours after pramlintide injection Follow-up: Initially, patient should have at least monthly follow ups to ensure safety and efficacy Discontinue if patient has: O Less than a 10% decrease in HbA1c (unless glycemic target has been met) O Significant or frequent episodes of hypoglycemia O Has persistent or clinically significant nausea O Is noncompliant with SMBG, dosing adjustments, clinic appointments O Now has any of the exclusion criteria since starting pramlintide October 2005 VISN 20 P&T Committee	
BL117	PRASUGREL ORAL TAB	EFFIENT	Criteria for Non-Formulary Use Prasugrel VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-	NON-FORMULARY

			making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services. (For additional details, refer to the Prasugrel Drug Monograph at www.pbm.va.gov or http://vaww.pbm.va.gov) FDA approved indication for use: To reduce the rate of thrombotic cardiovascular events including stent thrombosis in patients with acute coronary syndrome (ACS) (unstable angina [UA], non-ST elevation myocardial infarction [NSTEMI], or ST-elevation myocardial infarction [STEMI]) who are to be managed with percutaneous coronary intervention (PCI) Prasugrel is associated with an increased risk of major bleeding compared to clopidogrel. To date, prasugrel has been evaluated only in patients with acute coronary syndrome (ACS) and undergoing percutaneous coronary intervention (PCI) and may be considered as an alternative to clopidogrel in these patients meeting the criteria specified below. Prasugrel is not recommended for use outside the indications below (see criteria) until further evidence is available evaluating the efficacy and safety of prasugrel for other situations (clopidogrel remains the thienopyridine of choice for these other indications). Providers must weigh the potential benefits and risk of bleeding in consideration of prasugrel use. Requests for prasugrel initiated outside of the VA should be evaluated based upon VA criteria for use. EXCLUSION CRITERIA (If one is selected, patient is not eligible) Contraindications: O Active pathological bleeding (e.g., peptic ulcer or intracranial hemorrhage [ICH]) O History of previous transient ischemic attack (TIA) or stroke Lack of net clinical benefit and/or harm observed in the following situations: O Anticipated coronary artery bypass graft (CABG) surgery within 7 days O Age of >/= 75 yrs, unless patient is deemed at high risk of recurrent ischemic events (e.g., diabetes [DM] or prior myocardial infarction [MI]) and otherwise low bleeding risk Situations associated with an increased risk of bleeding (excluded from the pivotal clinical trial [TRITON-TIMI 38]): O Recent fibrinolytic therapy (within 24 hrs of fibrin-specific therapy [e.g., alteplase, reteplase, tenecteplase] or within 48 hrs of non-fibrin-	

			specific therapy [e.g., urokinase]) O Active internal bleeding or bleeding diathesis O Intracranial neoplasm, arteriovenous malformation, or aneurysm O International Normalized Ratio (INR) >1.5 O Platelet count /= 3a O Either ST segment deviation of >/= 1 mm or elevated cardiac biomarkers of necrosis 3. Stent thrombosis as follows: The following must be selected for patient to be eligible: O Definite or probable acute stent thrombosis (ARC definitionb) in patients documented to be compliant with aspirin and clopidogrel (combination therapy with prasugrel plus aspirin is indicated) PRECAUTIONS O Interruption or discontinuation: Prasugrel should be discontinued for active bleeding, elective surgery, TIA or stroke. However, in patients managed with PCI and stent placement, interruption or premature discontinuation of anti-platelet medications has been associated with an increased risk of stent thrombosis, MI, and death. Lapses in therapy should be avoided unless there is clinical rationale otherwise. O General increased bleeding risk: Prasugrel has been shown to be associated with an overall increased risk of bleeding compared to clopidogrel, including life-threatening and fatal bleeding. Benefits and risks should be considered by patient and provider. O Advanced age (>/=75 yrs): Increased risk of life-threatening and fatal bleeding has been shown with unclear benefit; prasugrel should generally be avoided unless a high risk patient (e.g., DM or prior MI), where benefits and risks should be considered O Low body weight (70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter > 50mm or left ventricular ejection fraction [LVEF] < 40%), who are in sinus rhythm or who will be cardioverted. EXCLUSION CRITERIA (if ONE is checked, patient is not eligible) o New York Heart Association (NYHA) Class IV heart failure (HF) or NYHA Class II-III HF with recent decompensation requiring hospitalization or referral to a specialized HF clinic (Boxed Warning) o Second or third degree atrioventricular block or sick sinus syndrome (except in conjunction with a pacemaker) o Significant bradycardia (e.g., < 50 bpm) o Receiving concomitant strong CYP 3A inhibitor (e.g., ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazadone, and ritonavir) o Uncorrected hypokalemia or hypomagnesemia o QTc Bazett > 500 ms with appropriate correction for prolongation of QRS interval in patients with	

			intraventricular conduction delay and ventricular pacing o Receiving concomitant medications that may prolong the QT interval and increase the risk of torsade de pointes (e.g., phenothiazine antipsychotics, tricyclic antidepressants, certain oral macrolide antibiotics, Class I and III antiarrhythmic agents) o Severe hepatic impairment (i.e., Child-Pugh Grade C or baseline LFTs > 2 X upper limit normala) o Long standing (> 1 year duration) atrial fibrillation without proven successful cardioversion, unless patient is being considered for cardioversion o Pregnancy (Category X) o Nursing mothersb INCLUSION CRITERIA (must fulfill ALL the following to be eligible) o Initial prescription restricted to VA Cardiology or local designee (monitoring must be documented by a VA provider) o Symptomatic recurrent paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL) documented by ECG within the past 6 months, with a second ECG in sinus rhythm or pending cardioversion o Intolerance (e.g., unmanageable significant adverse event), contraindication to, or ineffective therapy with at least one other antiarrhythmic agent used for the rhythm management of AF (refer to pharmacologic management considerations for AF in the table below) Considerations for Pharmacologic Maintenance of Sinus Rhythm in Patients with Recurrent Paroxysmal or Persistent AF1,2 No or minimal Hypertensive heart disease structural heart disease with substantial LVH First line therapy3 Flecainide Amiodarone Propafenone Dronedarone4 Sotalol Second line therapy Amiodarone Dofetilide Dronedarone5 CAD HF* First line therapy3 Dofetilide Amiodarone Sotalol Dofetilide Second line therapy Amiodarone Dronedarone5 1Adapted from ACC/AHA/ESC 2006 guidelines for the management of patients with AF. Circulation 2006;114:e257-e354 2 Recommendations are not intended for switching patients who are stable on current therapy 3 One or more of the agents listed should be considered prior to considering second line therapy; treatment selections listed alphabetically, not in order of preference 4Dronedarone is Nonformulary in the VA. Dronedarone may be an alternative in patients who are intolerant to the recommended first-line VA National Formulary treatment with amiodarone in this patient population; in addition, dronedarone may be considered prior to amiodarone in a younger (e.g., < 60 years of age) patient on a case by case basis, subject to local adjudication 5Dronedarone is Nonformulary in the VA:	

			medications on the VA National Formulary should be considered prior to treatment with Nonformulary agents. Dronedarone may be considered prior to amiodarone in a younger (e.g., < 60 years of age) patient on a case by case basis, subject to local adjudication 6Dronedarone is contraindicated in patients with NYHA Class IV HF or NYHA Class II-III HF with recent decompensation requiring hospitalization or referral to a specialized HF clinic (Boxed Warning); the safety of dronedarone in patients with AF and LVEF < 35% is unknown: inclusion criteria for ANDROMEDA approximated LVEF < 35%, and found an increase in mortality with dronedarone vs. placebo; only ~ 12% patients included in ATHENA had LVEF < 45% with subgroup evaluation in patients with LVEF < 35% (~4% of patients enrolled) that did not find a difference between dronedarone and placebo in the primary endpoint of first hospitalization due to CV events or death. As the LVEF may fluctuate in patients with AF (i.e., LVEF may fall into the range that puts a patient at high risk), this should be taken into account when considering treatment with dronedarone For women of childbearing potential, o serum pregnancy test should be performed prior to receiving dronedarone o use of an effective method of contraception during dronedarone therapy DOSING RECOMMENDATIONS The recommended dose of dronedarone is 400 mg administered twice daily with the morning and evening meals MONITORING Assess for adequate symptom control (e.g., frequency or duration of palpitations/irregular heartbeat, time to recurrence) Evaluate for signs or symptoms of new or worsening HF; risk for serious adverse events unclear in patients who may experience transient decreases in ejection fraction ECG for QT prolongation (dronedarone should not be used if QTc Bazett > 500 ms) ECG for normal sinus rhythm; dronedarone should not be used for treatment of long standing (> 1 year duration) atrial fibrillation without proven successful cardioversion; if patient remains in atrial fibrillation while on dronedarone, they should be referred back to and/or provider should consult with Cardiology Heart rate for bradycardia (it is recommended that dronedarone be discontinued if significant bradycardia; e.g., < 50 bpm) Serum electrolytes for hypokalemia or hypomagnesemia, if receiving potassium depleting diuretics Serum creatinine for potential increase of 0.1 mg/dl (reported to plateau 7days after initiation; without an effect on GFR) Dronedarone should be used with	

			caution in patients with moderate hepatic impairment (i.e., Child-Pugh Class B) due to an increase in dronedarone exposure with wide variability in drug exposure that may increase the risk for adverse events. These patients should be monitored closely for increase in liver enzymes (AST/ALT) > 2 X upper limit normalb and > 0.5 X upper limit normal from baseline values Drug Interactions o Warfarin: although there was no clinically significant increase in INR in a single-dose study in healthy individuals administered dronedarone in conjunction with warfarin, additional monitoring and/or dose adjustments of warfarin may be warranted in patients receiving dronedarone given VA ADERS reports of a probable drug interaction with elevated INRs and bleeding o CYP 3A inhibitors or inducers: in addition to being contraindicated in patients receiving concomitant strong CYP 3A inhibitors (refer to exclusion criteria), it is recommended that dronedarone not be administered with moderate CYP 3A inhibitors (e.g., diltiazem, verapamil, grapefruit juice) or CYP 3A inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, St. John's Wort) o Substrates of CYP 3A, 2D6, or P-glycoprotein (P-gP): dronedarone may inhibit P-gP, and is also a moderate inhibitor of CYP 3A and CYP 2D6 and can therefore interact with substrates of these enzyme systems including some statins (it is recommended that the labeling recommendations be followed according to the respective statin for use with CYP 3A and P-gP inhibitors), sirolimus, tacrolimus and other medications metabolized by CYP 3A; beta-blockers, tricyclic antidepressants, SSRIs metabolized by CYP 2D6. If dronedarone is used in combination with digoxin (P-gP substrate), it is recommended the dose of digoxin be halved; monitor digoxin levels and for toxicity Discuss risk vs. benefit of therapy in patients of child-bearing potential and appropriate methods of contraception RECOMMENDATIONS FOR DISCONTINUATION Patient does not experience adequate symptom control (e.g., no or inadequate change in frequency or duration of palpitations/irregular heartbeat; no or inadequate increase in time to recurrence AF/AFL) Patient experiences a significant drug related adverse event a Dronedarone has not been studied in patients with baseline LFTs > 2 X upper limit normal b It is unknown if dronedarone is excreted in human milk; due to the number of medications that are excreted in human milk and the potential for serious adverse reactions that may	

			occur if a nursing infant is exposed to the drug, the risk vs. benefit of whether the mother should discontinue nursing or to begin dronedarone should be discussed May 2010 VISN 20 P&T	
CV350	PRAVASTATIN	PRAVACHOL	NON-FORMULARY, CFU NON-FORMULARY, CFU	NON-FORMULARY
OP300	PREDNISOLONE OPH SOLN	INFLAMASE FORTE	Non-Formulary: no criteria for use	NON-FORMULARY
HS051	PREDNISOLONE ORAL	PEDIAPRED	Non-Formulary: no criteria for use	NON-FORMULARY
OP350	PREDNISOLONE/SULFACETAMIDE OPH SUSP	BLEPHAMIDE	Non-Formulary: no criteria for use	NON-FORMULARY
CN000	PREGABALIN ORAL CAPSULE	LYRICA	Criteria for Non-Formulary Use of Pregabalin VHA MAP/PBM-SHG Exclusion Criteria: If the answer to ANY item below is met, then the patient should NOT receive pregabalin. - Hypersensitivity to pregabalin or product components. - Use of pregabalin for chronic low back pain, chronic pain due to osteoarthritis of the hip, or panic disorder. - Use of pregabalin in combination with gabapentin. Inclusion Criteria: One of the following criteria sets (A-D) must be fulfilled. A. Patient has painful diabetic neuropathy AND has well documented insufficient response despite an adequate trial at maximally tolerated doses of gabapentin (up to 3600 mg/d) AND at least one oral agent that is not classified as a controlled substance, used alone or in combination, from 1 of the 3 drug classes shown below (minimum total of 2 oral agents including gabapentin) OR patient has documented intolerance, hypersensitivity, or contraindication to gabapentin and the following agents and is therefore precluded from undertaking an adequate trial of at least one oral agent from 1 of the 3 drug classes. Painful Diabetic Neuropathy (treatment duration: 6-12 wk) Gabapentin (up to 3,600 mg/d) AND at least one oral agent from 1 of the 3 drug classes below: 1) Antidepressants, tricyclic: e.g., amitriptyline (nortriptyline) 25-150 mg/day; desipramine 12.5-200 mg/day; imipramine 25-225 mg/day. Tricyclic antidepressants are reasonable options in patients less than 65 years old. 2) Antiepileptic drugs (AEDs): e.g., carbamazepine 200-600 mg/day, phenytoin 300 mg/day, valproate 500-1,200 mg/day. These AEDs only apply to patients who may already have had trials of these agents. New trials of these agents are not required. 3) Opioid: e.g., tramadol 50-400 mg/day. The criteria suggest tramadol, a nonscheduled opioid, as a prior treatment alternative to pregabalin. The criteria do not recommend a prior	NON-FORMULARY

			trial of schedule II to IV opioids before considering pregabalin. However, patients already prescribed schedule II to IV opioids may be considered for pregabalin therapy as long as the minimum of 2 prior agents is met. B. Patient has postherpetic neuralgia, requires systemic therapy, AND has a well documented intolerance, hypersensitivity, contraindication, or insufficient response despite an adequate trial at maximally tolerated doses of gabapentin. Patients with localized postherpetic neuralgia should also have had a well documented intolerance, hypersensitivity, contraindication, or insufficient response despite a prior adequate trial of either one of the topical agents indicated below. Postherpetic Neuralgia, Oral Agents (treatment duration: 6-8 wk) 1) Antiepileptic drugs: gabapentin 1,200-3,600 mg/day Note: Tricyclic antidepressants are reasonable options in patients less than 65 years old: e.g., amitriptyline (nortriptyline) 25-150mg/day; desipramine 12.5-200 mg/day; imipramine 25-225 mg/day Localized Postherpetic Neuralgia, Topical Agents 1) Capsaicin cream 0.075%: apply 3 to 4 times daily for at least 6 wk 2) Lidocaine patch 5%: apply up to 3 patches, only once for up to 12 h, within a 24-h period. C. Patient has partial-onset seizure disorder, is concurrently treated with at least one other antiepileptic drug, and has a well documented intolerance, hypersensitivity, contraindication, or insufficient response despite an adequate trial at maximally tolerated doses of at least 2 of the agents listed below. Partial-onset Seizures, Adjunctive Therapy (treatment duration: 12 wk) Carbamazepine, gabapentin, lamotrigine, levetiracetam, phenytoin, topiramate, valproate D. Patient has a documented diagnosis of fibromyalgia and meets all of the following criteria: 1) Moderate to severe fibromyalgia symptoms 2) Trial of gabapentin and one other evidence-based effective agent (e.g., amitriptyline, SSRIs, tramadol 1 acetaminophen) 3) Previous or concurrent trial of at least one type of guideline-concordant nonpharmacologic therapy shown to be effective in the management of fibromyalgia (e.g., cardiovascular fitness exercise program, cognitive behavioral therapy). Since pregabalin has been shown to lack significant antidepressant and antianxiety effects in patients with fibromyalgia, providers should consider the use of tricyclic, SSRI, antidepressants for management of patients with fibromyalgia and concurrent depression. Use of these agents with pregabalin may result in

			additive central nervous system depressant effects. Discontinuation Criteria No benefit after up to 12 weeks of treatment with pregabalin at maximally tolerated doses. Refills Prescribers need to evaluate the efficacy of the initial prescription before prescriptions with refills are allowed. Evaluate on a case-by-case basis Use of pregabalin for conditions other than those covered in the criteria above. Dosing in normal renal function (CrCl >/= 60 ml/min) Parameter D. Neurop. P-Herp. neuralgia P-O seizures Fibromyalgia Initial daily dose 50mg tid 75mg bid/50mg tid 75mg bid/50mg tid 75mg bid Maximum daily dose 300mg/d 600mg/d 600mg/d 450mg/d Consult appropriate references for dosing in patients with renal impairment. March 2008 VISN 20 P&T Committee	
CV300	PROCAINAMIDE HCL 1GM ER TAB	PROCANBID	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CV300	PROCAINAMIDE HCL 250MG CAP	PRONESTYL	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

CV300	PROCAINAMIDE HCL 500MG CAP	PRONESTYL	Non-Formulary: no criteria for use	NON-FORMULARY
CV300	PROCAINAMIDE HCL 500MG ER TAB	PROCANBID	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CV300	PROCAINAMIDE HCL 750MG SA TAB	PROCAN SR	Non-Formulary: no criteria for use	NON-FORMULARY
HS800	PROGESTERONE INTRAUTERINE INSERT	PROGESTASERT		NON-FORMULARY
CN101	PROPOXYPHENE ORAL PRODUCTS	DARVON, DARVOCET-N	National Criteria for Non-Formulary Use of Propoxyphene A summary of the literature review used to support the criteria for use of propoxyphene is available at http://www.pbm.va.gov . Although propoxyphene is considered to be a weak opioid, it can cause deaths???often sudden deaths???related to drug overuse (e.g., taking more than prescribed doses), misuse, and moderate, accidental, and intentional overdoses. These deaths often, but not always, occurred when propoxyphene was taken concurrently with alcohol or other CNS depressants. Because of these drug-related deaths, unlike other opioids, propoxyphene has a Boxed Warning advising providers to avoid use in patients who are suicidal or addiction-prone. Propoxyphene and its metabolite, norpropoxyphene, are cardiotoxic and neurotoxic. Drug and metabolite serum concentrations increase with repeated dosing and in renal or hepatic impairment. EXCLUSION CRITERIA: Patients who meet any of the following exclusion criteria should NOT receive propoxyphene: 1. Current history of suicidal ideation, suicide attempt, or depression 2. History or propensity of drug overuse (e.g., taking more than prescribed doses), misuse, abuse, addiction/dependence, or diversion 3. Current diagnosis of alcohol abuse or dependence 4. Current or past history of seizures 5. Impairment of renal or hepatic function. No specific	NON-FORMULARY

			recommendations exist for appropriate dosage adjustments in these situations. 6. More than 4 doses per day or greater than 390 mg per day of propoxyphene HCl (600mg per day propoxyphene napsylate) is required for pain relief. Weigh Risks Versus Benefits and Use Caution: Use caution when prescribing propoxyphene in patients with the following characteristics: 1. Past history of suicidal ideation, suicide attempt, or depression or current or past history of emotional disturbances or other psychiatric disorder 2. Concurrent treatment with sedatives, tranquilizers, muscle relaxants, antidepressants, or other CNS-depressant drugs. Caution patients about additive CNS-depressant effects. 3. Excessive alcohol intake or distant history of alcohol abuse or dependence. Advise patients to limit their intake of alcohol, and caution them about additive CNS depressant effects. 4. Pregnant or nursing 5. Use in the elderly (due to decreased metabolism). Consider using less frequent dosing intervals. 6. Current or past history of cardiac arrhythmias or prolonged conduction times on ECG (QRS interval) 11/17/2006 VISN 20 P&T	
CV100	PROPRANOLOL INJ	INDERAL	Non-Formulary: no criteria for use	NON-FORMULARY
RE200	PSEUDOEPHEDRINE 12 HOUR XR TABS	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
CV300	QUINIDINE GLUCONATE 80MG/ML INJ	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AP101	QUININE SULFATE 325MG CAP	N/A	Quinine is non-formulary, restricted to the treatment of malaria. Feb 2007 VISN 20 P&T Committee	NON-FORMULARY
GA900	RABEPRAZOLE 20MG EC TAB	ACIPHEX	Non-Formulary: no criteria for use	NON-FORMULARY
XA199	RADIACARE GEL TUBE AND SHEET	RADIACARE	Non-Formulary: no criteria for use	NON-FORMULARY
HS900	RALOXIFENE ORAL	EVISTA	Raloxifene is non-formulary, restricted to patients who are intolerant or have contraindications to hormone replacement therapy (HRT) and alendronate. The concurrent use of raloxifene and HRT is not recommended.	NON-FORMULARY
CN309	RAMELTEON ORAL TAB	ROZEREM	Non-Formulary: no criteria for use	NON-FORMULARY

CN800	RAMIPRIL ORAL	ALTACE	Ramipril is restricted to PBM/MAP criteria: Ramipril should be used only as adjunctive therapy for patients who do not meet the exclusion criteria below, who require no additional blood pressure reduction, and who have any one of the following: coronary artery disease (CAD); stroke; peripheral vascular disease (PVD); and/or high risk patients with type 2 diabetes mellitus (DM). Exclusion criteria: Patients are not appropriate for treatment with ramipril if one of the following is present: chronic heart failure (HF) or left ventricular ejection fraction (LVEF)	NON-FORMULARY
CV250	RANOLAZINE SA TAB	RENEXA	Nonformulary Criteria for Use Checklist Ranolazine VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives FDA APPROVED INDICATION FOR USE Ranolazine is indicated in the treatment of chronic stable angina EXCLUSION CRITERIA (If one is selected, patient is not eligible) 0 Clinically significant hepatic impairment 0 Receiving strong CYP 3A4 inhibitors including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir. 0 Receiving strong CYP 3A4 inducers including rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine, or St. John's wort. INCLUSION CRITERIA (Both must be selected to be eligible) 0 Anginal episodes an average of 3 or more times per week despite maximal or maximally tolerated anti-anginal drug therapy (Defined as treatment with a beta-blocker, long-acting dihydropyridine calcium channel blocker and a long-acting nitrate). 0 A VA healthcare provider is actively involved in the monitoring and management of ranolazine therapy and will re-assess ranolazine's therapeutic effectiveness and tolerability within 12 weeks after initiation of therapy. PRECAUTIONS 0 QT-interval prolongation: Ranolazine can prolong the QT interval in a dose-dependent manner. The mean increase (QTc) seen with 1000 mg twice daily was 6 milliseconds. There is little experience with ranolazine use in patients with pre-existing QT interval prolongation (Normal QTc	NON-FORMULARY
MS300	RAPACURONIUM INJ	RAPLON	Non-Formulary: no criteria for use	NON-FORMULARY
CN500	RASAGILINE ORAL TAB	AZILECT	Non-Formulary: no criteria for use	NON-FORMULARY

HS502	REPAGLINIDE	PRANDIN	Repaglinide is non-formulary, restricted to: (1) patients with renal insufficiency (serum creatinine greater than 2.0 mg/dL). These patients should start at the lower end of the dose range (i.e., 0.5 mg before meals), and be titrated upwards carefully, (2) patients with an elevated hemoglobin A1c (> 7.5) and repeated hypoglycemia on sulfonylureas, OR (3) patients with normal fasting glucose values, postprandial hyperglycemia, and elevated HbA1c values (> 7.5). Repaglinide should be used as monotherapy for criteria 1 & 2, and may be combined with metformin or a glitazone for criterion 3. Patients who fail sulfonylurea therapy should not be prescribed repaglinide. The FDA has reported that concomitant use of gemfibrozil and repaglinide may result in enhanced and prolonged blood glucose lowering effects of repaglinide due to increase in repaglinide blood levels. For patients already on repaglinide and gemfibrozil, blood glucose levels should be monitored and repaglinide dose adjusted as needed. April 2004	NON-FORMULARY
DE101	RETAPAMULIN 1% TOPICAL OINTMENT	ALTABAX	Non-Formulary: no criteria for use	NON-FORMULARY
AM800	RIBAVIRIN INHALATION SOLUTION	VIRAZOLE	Restricted to ID Service or local equivalent	NON-FORMULARY
AM900	RIFAXIMIN	SALIX	NON-FORMULARY	NON-FORMULARY

AM900	RIFAXIMIN ORAL TAB	XIFAXAN	National Rifaximin Criteria: EXCLUSION CRITERIA - Known hypersensitivity to rifaximin. INCLUSION CRITERIA Refractory to lactulose (Select both to be eligible): - Patient continues to experience hepatic encephalopathy despite receiving lactulose at a dose that obtains 2 - 3 loose stools per day. - Both endpoints (persistent symptoms of hepatic encephalopathy and number of loose stools per day) are documented in patient's medical record. or Intolerance to lactulose (Select both to be eligible): - Patient with 4 or more loose stools per day despite dosage reductions. - Both endpoints (number of loose stools per day and dosage adjustments) are documented in the patient's medical record. DOSAGE AND ADMINISTRATION Rifaximin 400 mg orally three times daily. This can be taken with or without food. Prescription should be limited to no more than a 3 month supply. RECOMMENDED MONITORING After evaluating for initial response and tolerability, reassess medical treatment for hepatic encephalopathy every 3 months to confirm on-going need of rifaximin therapy. In addition to assessing the clinical signs and symptoms of hepatic encephalopathy, it is important to monitor the hydration status and electrolytes of the patient. November 2007 VISN 20 P&T Committee	NON-FORMULARY
IM600	RILONACEPT INJ	ARCALYST	Non-Formulary: no criteria for use	NON-FORMULARY
CN900	RILUZOLE ORAL	RILUTEK	Riluzole (Rilutek) is formulary, restricted to Neurology or locally designated subject matter expert for the treatment of ALS. VISN 20 P&T October 2009	NON-FORMULARY
CN709	RISPERIDONE ORAL DISINTEGRATING TABS (ODT)	RISPERDAL	VISN 20 Guidelines for Atypical Antipsychotics Atypical antipsychotics are restricted to the treatment of first episode psychosis or chronic psychosis in relapse. (national guidelines) First (and 2nd) line atypical antipsychotics: (alphabetical, no prescribed hierarchy) Aripiprazole Quetiapine Risperidone Ziprasidone 3rd line Olanzapine	NON-FORMULARY

Clozapine (if poor response to AT LEAST 2 other atypical antipchotics)

April 2007 VISN 20 P&T Committee

VISN 20 Guidelines for
Screening and Monitoring Patients Prescribed Atypical Antipsychotics

Baseline Screening Guidelines

Prior to initiating a new atypical antipsychotic, it is recommended that
clinicians:

1. Obtain/review the patient's personal and family history of obesity, diabetes, dyslipidemia, hypertension, or cardiovascular disease.

2. Provide basic education about signs and symptoms of
Hyperglycemia
Diabetic ketoacidosis

3. Obtain or document in CPRS baseline measures for
Fasting lipid panel and fasting blood sugar (or an HgA1C if it is difficult to get the patient's cooperation for a fasting blood sugar)
Weight (entered into CPRS Cover Sheet)
Height (entered into CPRS Cover Sheet)
Blood pressure (entered into CPRS Cover Sheet)

Subsequent Monitoring Guidelines

During the first 4 months of treatment, it is recommended that clinicians:

1. Obtain a fasting blood sugar and lipid panel at least once.
2. Record weight at each visit; note any increases.
3. Record blood pressure at least once.

At one year of treatment, it is recommended that clinicians:

			1. Make sure that a recent weight and blood pressure are recorded in the chart. 2. Repeat fasting glucose. 3. Order a lipid panel if there are concerns about significant weight gain, personal or family risk factors for cardiovascular disease, or past abnormal laboratory results. After one year, monitoring is at the clinician's discretion. Considerations that would warrant further annual or more frequent screening include: 1. Significant amount of weight gain or pre-existing obesity 2. Family or personal history of other significant risk factors for cardiovascular disease or diabetes 3. Past abnormal laboratory screening results Summary of VISN 20 Screening and Monitoring Recommendations Measure Baseline First 4 Months One Year Personal/Family History Yes Review any changes Patient/Family Education Yes Height Yes Weight (BMI) Yes Each visit Yes Fasting glucose/ Hgb A1c Yes At least once Yes Fasting lipid profile Yes At least once If clinically indicated Blood pressure Yes At least once Yes June 2005 VISN 20 P&T	
CN900	RIVASTIGMINE ORAL CAPSULE	EXELON	VA NATIONAL CRITERIA FOR CHOLINESTERASE INHIBITORS Galantamine is first-line, with criteria below. Donepezil is second-line for patients who meet the same criteria but cannot be treated with galantamine. Rivastigmine and tacrine are non-formulary. VA National Criteria for Use: Cholinesterase Inhibitors to Treat Dementia Initial Prescription (all of	NON-FORMULARY

			the following must be met): 0 A diagnosis of Alzheimer's disease (AD), mixed (AD and vascular) dementia, Lewy Body Dementia, or dementia associated with Parkinson's disease 0 The patient is able to perform >1 activity of daily living with minimal assistance 0 For patients with a FAST Score of 5 or 6, the patient has a regular caregiver(s) to assist with medication and care or resides in a setting where assistance with medication administration is provided such as a nursing home. FAST link: http://vaww.national.cmop.va.gov/PBM/Clinical %20Guidance/Drug%20 Monitoring/Functional %20Assessment%20Staging%20 (FAST)%207.31.08.doc. 0 The patient's medication regimen has been reviewed and all unnecessary anticholinergic medications have been discontinued. 0 No exclusion criteria are met. Renewal Every 6 Months (all must be met with the noted exception): 0 The dementia diagnosis has not changed 0 The patient is taking a therapeutic dose 0 The patient is able to perform >1 activity of daily living with minimal assistance 0 For patients with a FAST Score of 5 or 6, the patient has a regular caregiver(s) to assist with medication and care 0 The patient and/or caregiver and prescriber agree that the patient has benefited from the cholinesterase inhibitor and wish to continue, i.e., continuation is still in line with the goals of treatment and treatment targets. This discussion and decision are documented in the patient's medical record. 0 The patient's medication regimen has been reviewed and all unnecessary anticholinergic medications have been discontinued. 0 No exclusion criteria are met. Exception: If during a trial off a cholinesterase inhibitor, rapid deterioration or worsening of psychiatric symptoms or behavioral disorders is noted, then the activities of daily living criterion is not relevant. Combination Treatment with Memantine (all of the following must be met): 0 The patient is determined to have moderate to severe Alzheimer's disease (FAST Stage 5 or 6) 0 Has been on a therapeutic dose of cholinesterase inhibitor or memantine for >6 months 0 The patient is able to perform >1 activity of daily living with minimal assistance 0 The patient has a regular caregiver(s) to assist with medication and care Exclusion Criteria (any of the following): 0 Bradycardia (	
CN900	RIVASTIGMINE TREANSDERMAL PATCH	EXELON PATCH	VA NATIONAL CRITERIA FOR CHOLINESTERASE INHIBITORS Galantamine is first-line, with criteria	NON-FORMULARY

			below. Donepezil is second-line for patients who meet the same criteria but cannot be treated with galantamine. Rivastigmine and tacrine are non-formulary. VA National Criteria for Use: Cholinesterase Inhibitors to Treat Dementia Initial Prescription (all of the following must be met): 0 A diagnosis of Alzheimer's disease (AD), mixed (AD and vascular) dementia, Lewy Body Dementia, or dementia associated with Parkinson's disease 0 The patient is able to perform >1 activity of daily living with minimal assistance 0 For patients with a FAST Score of 5 or 6, the patient has a regular caregiver(s) to assist with medication and care or resides in a setting where assistance with medication administration is provided such as a nursing home. FAST link: http://vaww.national.cmop.va.gov/PBM/Clinical%20Guidance/Drug%20 Monitoring/Functional%20Assessment%20Staging%20(FAST)%207.31.08.doc. 0 The patient's medication regimen has been reviewed and all unnecessary anticholinergic medications have been discontinued. 0 No exclusion criteria are met. Renewal Every 6 Months (all must be met with the noted exception): 0 The dementia diagnosis has not changed 0 The patient is taking a therapeutic dose 0 The patient is able to perform >1 activity of daily living with minimal assistance 0 For patients with a FAST Score of 5 or 6, the patient has a regular caregiver(s) to assist with medication and care 0 The patient and/or caregiver and prescriber agree that the patient has benefited from the cholinesterase inhibitor and wish to continue, i.e., continuation is still in line with the goals of treatment and treatment targets. This discussion and decision are documented in the patient's medical record. 0 The patient's medication regimen has been reviewed and all unnecessary anticholinergic medications have been discontinued. 0 No exclusion criteria are met. Exception: If during a trial off a cholinesterase inhibitor, rapid deterioration or worsening of psychiatric symptoms or behavioral disorders is noted, then the activities of daily living criterion is not relevant. Combination Treatment with Memantine (all of the following must be met): 0 The patient is determined to have moderate to severe Alzheimer's disease (FAST Stage 5 or 6) 0 Has been on a therapeutic dose of cholinesterase inhibitor or memantine for >6 months 0 The patient is able to perform >1 activity of daily living with minimal assistance 0 The patient has a regular	

			caregiver(s) to assist with medication and care Exclusion Criteria (any of the following): 0 Bradycardia (	
CN105	RIZATRIPTAN 10MG TAB, MLT WAFER	MAXALT	RIZATRIPTAN CRITERIA FOR USAGE Northwest Network 1. Rizatriptan, a 5HT-1D (serotonin) receptor agonist, is approved only for treatment of classic and common migraine. It is not used for basilar or hemiplegic migraine headaches. 2. Generally, the first dose should be given under medical supervision. If the first dose is given outside the VA, there should be some notification and documentation of the effectiveness of rizatriptan. 3. Patients can receive rizatriptan from a provider if NSAIDs, ergotamine, or dihydroergotamine (DHE) therapy have been shown to be ineffective or not tolerated. 4. Patients should not get rizatriptan if there is a contraindication such as ischemic heart disease (angina, history of MI, documented silent ischemia), Prinzmetal's angina, uncontrolled hypertension, pregnancy or women trying to get pregnant, or hypersensitivity. In addition, rizatriptan should not be used concomitantly with ergot-containing preparations or MAO inhibitors. 5. Rizatriptan has many potential adverse effects including: dizziness; drowsiness; fatigue; somnolence; systolic/diastolic blood pressure increases (5 to 10 mmHg) with 20mg or higher; paresthesia; chest pain; nausea/vomiting; and dry mouth. 6. Caution is advised when using rizatriptan in patients with hepatic insufficiency and/or renal failure. 7. In patients exhibiting one or more of the following risk factors, rizatriptan dosage will not be increased: hypertension; strong family history of CAD; hypercholesterolemia; obesity; post-menopausal women; diabetes; smoker; males > 40 years; and any other causes of headache. 8. In patients where more than 16 oral doses rizatriptan per month are desired, an alternate oral medication (sumatriptan) or sumatriptan IM/intranasal should be tried. If all forms of therapy have been tried, a non-formulary drug request must be submitted and approved by Neurology Service or local facility equivalent specialist prior to dispensing. 9. All patients requiring more than 16 oral doses per month	NON-FORMULARY

			should be reviewed for use of migraine prophylactic medications to include one or more of the following: divalproex (Depakote); propanolol (Inderal); amitriptyline (Elavil); or verapamil (Calan). When administering rizatriptan to a patient receiving propranolol therapy, the dose of rizatriptan should be 5mg, with a maximum daily dose of 15mg. July 1999	
MS102	ROFECOXIB ORAL	VIOXX	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
RE900	ROFLUMILAST	DALIRESP	NON-FORMULARY	NON-FORMULARY
BL116	ROMIPLOSTIN INJ	NPLATE	Criteria for Use: Thrombopoietin Agonists Eltrombopag (Promacta) and Romiplostim (Nplate) VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services. FDA-Approved Indication: Treatment of thrombocytopenia in patients with chronic immune (idiopathic)	NON-FORMULARY

			thrombocytopenic purpura (ITP) who had an insufficient response to corticosteroids, immune globulins or splenectomy. (For details, refer to the monographs: http://vaww.national.cmop.va.gov/PBM/Clinical %20Guidance/Drug%20Monographs /Eltrombopag.doc; http://vaww.national.cmop.va.gov/PBM/Clinical %20Guidance/Drug%20Monographs /Romiplostim%20 (Nplate)%20Drug%20Monograph.doc) EXCLUSION CRITERIA (If any are selected below, patient is not eligible for either drug) () 1. Active malignancy or stem cell disorder () 2. Patient has not received prior therapy as an attempt to increase platelet counts () 3. Thrombocytopenia secondary to bone marrow suppressive anticancer therapy, antibiotic therapy or other drugs () 4. Thrombocytopenia secondary to chronic liver disease () 5. Patient refuses to transfer hematology care to VA hematology/oncology provider () 6. Thromboembolic event within the prior year, unless evaluated by a hematology provider and deemed to be an appropriate candidate () 7. Patient is unable to comprehend and/or comply with dosing instructions () 8. Patient is non-compliant with appointments for blood work INCLUSION CRITERIA (Criterion #1, 2 and 3 must be met) () 1. Documented diagnosis of Idiopathic Thrombocytopenia Purpura (ITP), per American Society of Hematology (ASH) guidelines* () 2. Platelet count < 30,000 mm3 with high bleed risk characteristics per ASH guidelines ** () 3. Patient has failed to respond to at least two (2) prior therapies listed: Corticosteroids (unless contraindicated) Immune globulin (unless contraindicated) Splenectomy (unless contraindicated) Cytotoxic therapy (ie. azathioprine, cyclophosphamide, vincristine) Immune suppressant therapy (ie. cyclosporine, mycophenolate mofetil, rituximab) Other (ie. danazol) * Diagnosis of ITP is based on history, PE, CBC and exam of peripheral smear. Bone marrow aspiration is appropriate in patients over age 60 years and those considering splenectomy (Blood 1996; 88: 3) ** High bleed risk characteristics include age > 60 yrs and/or major risk factors for bleeding such as hypertension, peptic ulcer disease or a vigorous lifetyle (Blood 1996; 88: 3) DOSAGE AND ADMINISTRATION ELTROMBOPAG ROMIPLOSTIM Initial dose 50 mg PO once daily 1 mcg/kg (ABW) SQ weekly East Asian descendents 25 mg orally once daily Mod-severe hepatic 25 mg orally once daily insufficiency Dose adjustments based on platelet count < 50 x 10/L	

			increase daily dose by 25mg to maximum+ increase weekly dose by 1 mcg/kg 200 - 400 x 10/L increase daily dose by 25mg+ increase weekly dose by 1 mcg/kg > 400 x 109/L Hold eltrombopag++ Hold romiplostim Maximum dose 75 mg/day 10 mcg/kg/week Notes + Assess impact of dose adjustment following at least 2 weeks of eltrombopag therapy. ++ Increase frequency of platelet monitoring to twice weekly. Once platelet count < 150 x 109/L, reinitiate therapy at daily dose reduced by 25 mg. RECOMMENDED MONITORING ELTROMBOPAG ROMIPLOSTIM Monitoring prior to initiation of therapy Peripheral blood smear Peripheral blood smear Ocular exam CBC Serum liver tests (Tbili, AST, ALT) CBC Monitoring during therapy Peripheral blood smear weekly until stable, then monthly CBC weekly until stable, then monthly Serum liver tests every 2 wks until stable, then monthly Peripheral blood smear weekly until stable, then monthly CBC weekly until stable, then monthly Monitoring upon discontinuation of therapy CBCs weekly for at least four weeks (both drugs) ISSUES FOR CONSIDERATION Eltrombopag and romiplostim are non-formulary items. Patients considered high risk for thromboembolism. TPO agonists may further increase risk for thrombotic complications. Consider risk of potential thromboembolic event vs. benefit of reducing bleed risk in these cases. Drug-drug interactions Eltrombopag: Multiple interactions reported. Eltrombopag is a substrate of CYP1A2 and CYP2C8; an inhibitor of OATP1B1; an inhibitor of UDP-glucuronosyltransferases (UGTs); and chelates polyvalent cations. Refer to prescribing information for details of interactions and management (http://vaww.national.cmop.va.gov/PBM/Clinical %20Guidance/Drug%20Monograph s/Eltrombopag.doc) Romiplostim: None known Drug-food interactions Eltrombopag: Separate ingestion of food containing iron, calcium, aluminum, magnesium, selenium and zinc by at least 4 hours. Romiplostim: None known Non-responders Consider discontinuing romiplostim after four weeks at maximum dose (10 mcg/kg/wk) if platelet count has not increased to a sufficient level to prevent bleeding. Consider discontinuing eltrombopag after 6 weeks at maximum dose (75 mg/day) if platelet count has not increased to a sufficient level to prevent bleeding. Renal insufficiency Eltrombopag: safety/efficacy not studied; use with caution in those with renal impairment	

			Romiplostim: safety/efficacy not studied; use with caution in those with renal impairment Hepatic insufficiency Eltrombopag: clearance reduced in moderate-severe hepatic impairment; initial dose should be reduced to 25mg PO daily; monitor serum liver function tests as recommended Romiplostim: safety/efficacy not studied; use with caution in those with hepatic impairment Pregnancy or Nursing mothers Pregnancy Category C. Consider potential benefit to mother against potential risk to fetus. REMS programs; enrollment for patients, providers and institutions; for details, refer to http://vaww.national.cmop.va.gov/PBM/Special %20Handling%20Drugs/For ms/AIII tems.aspx Eltrombopag: Promacta CARES Romiplostim: NEXUS	
HS502	ROSIGLITAZONE ORAL	AVANDIA	Criteria for Non-formulary Use of Thiazolidinediones VHA Pharmacy Benefits Management Service and the Medical Advisory Panel Pioglitazone is the agent of choice for patients newly starting on a thiazolidinedione (TZD). For patients currently receiving rosiglitazone the decision to continue rosiglitazone should be made in light of the available data only after a discussion of the risks and benefits of this and alternate therapies with the patients. Exclusions (if ONE is selected, patient is not eligible) - Type 1 Diabetes Mellitus - Pre-diabetes: impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)1 - New York Heart Association (NYHA) Class III or IV heart failure - Evidence of active liver disease or an ALT > 2.5 x the upper limit of normal - Developed significant heart failure while taking another thiazolidinedione (TZD) - Experienced jaundice while taking another TZD Inclusions for patients with Type 2 diabetes The following must be acknowledged before proceeding - Fluid status must be monitored for all patients; however, extra vigilance is required for patients with NYHA Class I/II heart failure or patients with risk factors for heart failure and/or when combining a TZD with insulin. Both TZDs carry a Black Box Warning that use is not recommended in symptomatic heart failure. Use as monotherapy (both must be selected) - Is intolerant of or has contraindications to both sulfonylureas and metformin - Target value for HbA1c based on VA/DoD Guidelines http://www.oqp.med.va.gov/cpg/DM_base.htm is likely to be attainable based on clinical trial data Insulin may be considered at anytime prior to using a TZD; however, it should be considered if patient is	NON-FORMULARY

			symptomatic or a greater reduction beyond what is achievable by TZDs is desired. In the pivotal trials the AVERAGE decrease in HbA1c ranged from 0.6-0.8%. The mean decrease was greater in those with higher baseline HbA1c (e.g 2.5% in those with baseline HbA1c of 10%) Combination (2 drug) oral therapy - Target value for HbA1c based on VA/DoD Guidelines http://www.oqp.med.va.gov/cpg/DM_base.htm is likely to be attainable based on clinical trial data AND one of the following - Inadequate glycemic control on monotherapy with a sulfonylurea (at > 50% maximal dose or highest tolerated dose) AND is intolerant of or has contraindications to metformin - Inadequate glycemic control on monotherapy with metformin (at > 2g/d or highest tolerated dose) AND is intolerant of or has contraindications to sulfonylureas Insulin may be considered at anytime prior to using a TZD; however, it should be considered if patient is symptomatic or a greater reduction beyond what is achievable by TZDs is desired. In the pivotal clinical trials the AVERAGE decrease in Hba1c ranged from 0.5 -1.6% for the combination of a SU +TZD and 0.6-1.0% for metformin + TZD Triple oral therapy (all 3 must be selected) - Inadequate glycemic control on 2-drug therapy with a sulfonylurea (at > 50% maximal dose or highest tolerated dose) and metformin (at > 2g/d or highest tolerated dose) - Patient is not a good candidate for or refuses addition of insulin - Target value for HbA1c based on VA/DoD Guidelines http://www.oqp.med.va.gov/cpg/DM_base.htm is likely to be attainable based on clinical trial data In the triple oral therapy trials, the AVERAGE decrease in HbA1c ranged from 0.4 - 1.9% TZD + insulin - Evidence of insulin resistance (e.g. acanthosis nigricans, polycystic ovary disease, total insulin dose > 1 unit/kg/day or > 100 units/day - these doses are considered as guidance and are not intended as absolute) and not at target HbA1c goal OR - Inadequate glycemic control with insulin therapy (e.g. due to hypoglycemia, patient refusing intensification of insulin regimen) Consider use of metformin prior to a TZD unless contraindicated The dose of rosiglitazone when combined with insulin should not exceed 4mg daily. The dose of pioglitazone should begin at 15 or 30 mg once daily and titrated according to glucose response. In the clinical trials, where a TZD was added to insulin, the AVERAGE decrease in HbA1 ranged from 0.6 to 1.5%. In one study, HbA1c decreased by > 0.7% in 27% of patients.	

			The mean decrease in insulin dose was 23% (32% had at least a 30% decrease in insulin dose) Renewal Criteria A significant minority of patients do not have a response to TZDs; therefore, to continue use, meaningful improvement in glycemic control after 3-6 months of therapy in the absence of significant adverse events must be demonstrated. In the case of TZD + insulin in patients with significant insulin resistance, a meaningful decrease in insulin dose and/or improvement in glycemic control must be demonstrated. notes The use of TZDs to prevent the development of diabetes in this population is not recommended. Although rosiglitazone had recently been shown to reduce the frequency of diabetes in individuals with IFG/IGT, the incidence of adverse cardiovascular events (secondary outcome) was higher in those receiving rosiglitazone. Lifestyle interventions (diet and exercise), which have also been shown to be effective, should be emphasized and initiated first. If patient is near their glycemic goal (e.g.	
CV350	ROSUVASTATIN	CRESTOR	NON-FORMULARY, CFU NON-FORMULARY, CFU	NON-FORMULARY
CV350	ROSUVASTATIN ORAL	CRESTOR	Non-Formulary Criteria for Using Rosuvastatin in Place of Lovastatin, Simvastatin, or Pravastatin (1) Inadequate LDL-C lowering response to maximum dose pravastatin or fluvastatin (non-formulary) in patients receiving potent CYP 3A4 inhibitors. The initial dose in these patients should be 5 mg daily. (2) Rosuvastatin can be considered in those patients not meeting their LDL-C goals on maximum doses or maximally tolerated doses of simvastatin. Rosuvastatin is the preferred non-formulary high potency HMG for primary prevention of coronary events in patients with hypercholesterolemia. (3) The VA Medical Advisory Panel (MAP) has recommended that rosuvastatin 20 mg daily generally be the maximum daily dose of rosuvastatin in the veteran population until more safety data are available for the 40 mg dose. However, the 40 mg dose can be considered only after confirmation of compliance with the lipid-lowering regimen; after a careful assessment of the benefits and risks in an individual patient; and only if the patient has not met their LDL-C goal (VA/DoD Dyslipidemia Guideline) on 20 mg daily. Factors that can increase the risk for serious adverse events (myopathy and rhabdomyolysis) should be considered in the risk assessment. These factors include but are not limited	NON-FORMULARY

			to: increasing statin doses, drug-drug interactions, hypothyroidism, frailty, advanced age and renal impairment. In those patients on rosuvastatin 40 mg daily, the MAP recommends baseline and periodic urinary and renal function monitoring. If unexplained, persistent proteinuria is noted in a patient receiving rosuvastatin 40 mg daily, the manufacturer recommends reducing the dose of rosuvastatin. (4) Rosuvastatin is not a substrate for cytochrome P450 3A4 (CYP 3A4) and therefore is not vulnerable to interactions with potent CYP 3A4 inhibitors. However, there are other interactions and situations that can result in clinically significant increases in rosuvastatin's serum concentrations. As a result, the manufacturer has recommended dose limits or dosing guidance for rosuvastatin in these individuals (e.g., cyclosporine, gemfibrozil, antacids, severe renal impairment, hemodialysis, Asian Americans). Rosuvastatin Dosing in Special Circumstances* Special Circumstance Starting Daily Dose Maximum Daily Dose Those predisposed to myopathy 5mg 20mg (advanced age, renal impairment, hypothyroidism) Severe renal impairment (CrCl	
IM100	RUBELLA VIRUS VACCINE	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
CN400	RUFINAMIDE	BANZEL	NON-FORMULARY	NON-FORMULARY

RE102	SALMETEROL ORAL INHL	SEREVENT	VISN 20 Formoterol Criteria for Use: 1. Restricted to use in patients with a diagnosis of COPD or asthma who have one or more of the following: (a) Nocturnal symptoms; (b) Frequent need for PRN rescue medications (greater than 12 inhalations per day of a short-acting beta-2 agonist); (c) Persistent asthma symptoms with concurrent use of inhaled corticosteroid therapy; (d) Predictable exercise-induced symptoms requiring use of a short-acting beta-2 agonist. 2. Pharmacists should educate patients that long-acting beta-2 agonists are not intended for acute attacks, and label the medication appropriately. 3. Patients should have a concurrent prescription for a short-acting agent to use as a rescue medication. 4. Maximum fill of one device per month (60 doses). 5. The use of formoterol is absolutely contraindicated without the use of an asthma controller medication, typically an inhaled corticosteroid, in patients with asthma. Single-ingredient formoterol should only be used in combination with an asthma controller medication; it should not be used alone. VISN 20 Salmeterol Non-Formulary Criteria for Use: 1. Restricted to patients intolerant to formoterol. 2. Pharmacists should educate patients that long-acting beta-2 agonists are not intended for acute attacks, and label the medication appropriately. 3. Patients should have a concurrent prescription for a short-acting agent to use as a rescue medication. 4. Maximum fill of one device per month (60 doses). 5. The use of salmeterol is absolutely contraindicated without the use of an asthma controller medication, typically an inhaled corticosteroid, in patients with asthma. Single-ingredient salmeterol should only be used in combination with an asthma controller medication; it should not be used alone. May 2004, Sept 2006, June 2008, Mar 2010, May 2010 VISN 20 P&T Committee	NON-FORMULARY
TN499	SELENIUM ORAL TAB	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
GU900	SEVELAMER CARBONATE POWDER	RENVELA	FORMULARY, CFU	NON-FORMULARY
GA900	SIBUTRAMINE	MERIDIA	Non-Formulary Criteria for Use Checklist for Sibutramine (Meridia) Sibutramine is approved for the management of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a calorie deficit diet. Patients who meet or continue to meet the criteria-for-use, whose prescriber has completed a non-formulary request form, and who have been enrolled in the sibutramine registry	NON-FORMULARY

			can be dispensed sibutramine. Criteria-for-Use for Initial 30 Day Supply The patient is enrolled in a MOVE program or similar VA multidisciplinary weight loss program The patient's BMI is: Greater than or equal to 30 kg/m2 OR Greater than or equal to 27 kg/m2 with the presence of other co-morbid conditions affected by being over weight or obese such as controlled hypertension, diabetes, and dyslipidemia. The patient has no contraindications to sibutramine including: o Hypersensitivity to sibutramine o Not currently taking nor has taken a MAOI, SSRI, SNRI, a triptan or other medication that affects serotonin, or pseudoephedrine in the past 2-weeks. o Anorexia or bulimia nervosa o Uncontrolled hypertension (>145/90) o A history of coronary artery disease o A history of heart failure o A history of arrhythmia o A history of stroke o A history of narrow angle glaucoma The patient has been enrolled in the sibutramine safety registry by the pharmacy. Patients who fail to meet all these criteria are ineligible for treatment with sibutramine. ---------- Criteria for First Refill The patient has attended all safety follow-up appointments (at least one visit for BP, HR, and weight measurements within weeks 1 or 2 of treatment). The patient's resting systolic or diastolic blood pressure has not been elevated by more than 10 mm Hg or greater than 145/90 on two or more consecutive appointments. The patient's resting heart rate has not increased by more than 10 beats per minute on two or more consecutive appointments. After 4 weeks on a dose of sibutramine 10 mg per day the patient has lost at least 4 pounds. (If the patient has lost less than 4 pounds, the dose of sibutramine can be increased to 15 mg per day and reassessed in another 4 weeks.) The patient is not experiencing intolerable side effects. The patient has not contraindications to sibutramine. See initial 30 days. The patient wishes to continue sibutramine Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued. ---------- Criteria for Refills Every 30 Days x 4 months The patient has maintained their initial weight loss or has continued to lose weight. The patient has had at least one BP and HR measurement charted. The patient's resting systolic or diastolic blood pressure has not been elevated by more than 10 mm Hg or greater than 145/90 on two or more consecutive appointments. The patient's resting heart rate has not increased by more than 10 beats per minute on two or more consecutive appointments The	

			patient has attended monthly safety follow-up appointments for BP, HR and weight. The patient is not experiencing intolerable side effects. The patient wishes to continue sibutramine. The patient has not contraindications to sibutramine. The patient has been taking sibutramine for less than 2 years. Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued. ---------- Criteria for Continuation at 6 Months The patient has lost at least 5% of their initial body weight or an average of 1 lb. per week. The patient's resting systolic or diastolic blood pressure has not been elevated by more than 10 mm Hg or greater than 145/90 on two or more consecutive appointments. The patient's resting heart rate has not increased by more than 10 beats per minute on two or more consecutive appointments The patient has attended monthly safety follow-up appointments (BP, HR and weight recorded) The patient is not experiencing intolerable side effects. The patient wishes to continue sibutramine. The patient has not contraindications to sibutramine. The patient has been taking sibutramine for less than 2 years. If the patient meets all of these criteria, they are eligible to continue sibutramine for a maximum of 2 years (total) with refills every 90 days. ---------- Criteria for Refills Every 90 Days After 6 Months The patient has maintained at least 67% of their maximum weight loss to date. The patient's resting systolic or diastolic blood pressure has not been elevated by more than 10 mm Hg or greater than 145/90 on two or more consecutive appointments. The patient's resting heart rate has not increased by more than 10 beats per minute on two or more consecutive appointments The patient has attended monthly safety follow-up appointments (BP, HR and weight recorded) The patient is not experiencing intolerable side effects. The patient wishes to continue sibutramine. The patient has not contraindications to sibutramine. The patient has been taking sibutramine for less than 2 years. Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued. October 21, 2005 VISN 20 P&T Committee	
GU900	SILDENAFIL ORAL	VIAGRA	VISN 20 VARDEPDE5 INHIBITOR CRITERIA AND POLICY VARDENAFIL RESTRICTIONS: Vardenafil is available in VHA and on the VA National Formulary for the treatment of erectile dysfunction (ED). Alternative	NON-FORMULARY

			PDE5 inhibitors can be prescribed for patients who meet the criteria for an alternative agent. It is the responsibility of the prescribing clinician to ensure the patient has no contraindications to vardenafil or the PDE5 inhibitor being prescribed and that the patient understands the choices for the treatment of ED and the associated potential risks and benefits. Vardenafil should not be used in patients who require a PDE5 inhibitor for treatment of Primary Pulmonary Hypertension (PPH) or for treatment of erectile dysfunction (ED) and the patient has a congenital or acquired QT prolongation or taking a Class Ia or Class III anti-arrhythmic agent due to an increased risk of QT prolongation. Those patients should receive sildenafil if they meet appropriate guidelines for use. Before prescribing sildenafil for a patient with an increased risk of QT prolongation, providers should consider that QT prolongation effects may be a PDE5 inhibitor drug class effect. The drug interaction between PDE5 inhibitors and alpha blockers or major CYP3A4 inhibitors remain classified as significant drug interaction. Vardenafil is on the tablet splitting list, so patients should split these tablets if appropriate according to policy. For patients meeting ED criteria for a PDE5 inhibitor and on sildenafil but have not tried vardenafil, pharmacists have authority to automatically convert these patients to vardenafil and adjust refills appropriately according to the following guidelines: Sildenafil Vardenafil (no alpha blocker) Vardenafil (with alpha blocker) 25 mg 5 mg (1/2 10 mg tab) 2.5 mg (1/2 5 mg tab) 50 mg or 100 mg 10 mg (1/2 20 mg tab) 5 mg (1/2 10 mg tab) In the interest of patient safety, VA will only honor PDE5 inhibitor prescriptions written by VA prescribers after an appropriate clinical evaluation. In addition, associated with the clinical evaluation, the following also apply: Vardenafil (and other PDE5 inhibitors) prescriptions used for the management of ED are limited to 4 doses per month. Greater quantities may be approved when requested and justified on a case-by-case basis (e.g., couples trying to conceive, veterans with an inconsistent response to PDE5 inhibitors). This quantity limit does not apply to patients taking sildenafil for the management of pulmonary hypertension. Lost prescriptions will not be replaced in the time period they are intended for; a refill, if authorized, will be made available at the next scheduled refill date. In addition, any adverse event that occurs with vardenafil or another PDE5 inhibitor should be reported in the VA	

			Adverse Drug Event Reporting System (VA ADERS). The use of combination therapy with vardenafil and alprostadil for the same sexual encounter will be available on a non-formulary basis for patients who have not responded to each individual agent when used alone. Vardenafil Non-Responder Criteria [Feb 2007] The following are criteria-for-use to determine if a patient is a vardenafil non-responder. Vardenafil non-responders are to be offered a trial with a different PDE5 inhibitor. Patients who have previously responded to a different PDE5 inhibitor are to be offered treatment with that agent. 1. Patient has no concurrent drug interactions or is on stable alpha-blocker therapy a. Unable to achieve adequate response after 4 doses of vardenafil 20 mg OR b. Unable to tolerate vardenafil dose titration to 20 mg and an inadequate response to 4 doses of a lower dose of vardenafil. AND c. The provider or their representative has reviewed the proper use of vardenafil with respect to: o Timing of dosing o Use of sexual stimulation o Appropriate administration Note: If the provider finds any correctable problems with administration, the patient should be given a 4 dose re-trial at the maximum tolerated dose. 2. Patients taking concurrent CYP3A4 Inhibitors CYP3A4 inhibitor Max. dose vardenafil Ritonavir 2.5 mg/72 hrs Indinavir 2.5 mg/24 hrs Ketoconazole 400mg/day 2.5 mg/24 hrs Itraconazole 400 mg/day 2.5 mg/24 hrs Ketoconazole 200 mg/day 5 mg/24 hrs Itraconazole 200 mg/day 5 mg/24 hrs Erythromycin 5 mg/24 hrs a. Unable to achieve adequate response after 4 doses OR b. Unable to tolerate vardenafil and an inadequate response to 4 doses of a lower dose of vardenafil (if possible). AND c. The provider or their representative has reviewed the proper use of vardenafil with respect to: o Timing of dosing o Use of sexual stimulation o Appropriate administration Note: If the provider finds any correctable problems with administration, the patient should be given a 4 dose re-trial at the maximum recommended or tolerated dose. 3. Patients taking Class IA or Class III antiarrhythmics or with congenital or acquired QT prolongation. These patients should not receive vardenafil. Class Ia antiarrhythmics: procainamide, quinidine, disopyramide Class III antiarrhythmics: sotalol, amiodarone, dofetilide (ibutilide and bretylium also fall in this class, but are injectible drugs and would not be used in outpatients on vardenafil). References: 1. Carson CC, Hatzichristou	

			DG, Carrier S, et al. Erectile response with vardenafil in sildenafil nonresponders: a multicentre, double-blind, 12-week, flexible-dose, placebo-controlled erectile dysfunction clinical trial. BJU International 2004;94:1301-9. 2. Wespes E, Amar E, Hatzichristou D, et al. EAU guidelines on erectile dysfunction: An update. European Urology 2006;49:806-15. 3. VA Drug Class Review: Phosphodiesterase Type 5 Inhibitors available at: http://www.pbm.va.gov/reviews/PDE5InhibitorDrugClassReviewFinal12_27_05_2.pdf and http://vaww.pbm.va.gov/reviews/PDE5InhibitorDrugClassReviewFinal12_27_05_2.pdf VARDENAFIL POLICY To help VISN 20 sites maintain uniform (equal access) and portable pharmacy benefits, primary care providers (PCPs) may consider prescribing vardenafil for patients with erectile dysfunction (ED) in accordance with the VA Guidelines for the Management of Erectile Dysfunction. Prior to prescribing vardenafil, a focused history and physical exam should be performed. In addition, a patient should receive education regarding ED treatment options offered at the VA, either directly from his primary care provider or by observing an educational ED videotape. This education should all be documented in the medical record or on the restricted drug request form. In patients who complain of decreased libido and sexual desire, a total or bioavailable serum testosterone level should be obtained and documented to be within normal range prior to initiation of vardenafil. If testosterone levels are low, appropriate evaluation or endocrinological consultation should be obtained. Vardenafil is ABSOLUTELY CONTRAINDICATED in any patient taking nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or other nitrate-containing drug. This contraindication includes PRN prescriptions. Patients using nitrates should be encouraged to try a vacuum erection device. If patients on nitrates are willing to try other treatment options, they should be referred to the ED clinic or local facility equivalent. The primary care provider, however, should inform the patient that he will not be given vardenafil in the ED clinic and that if he is unwilling to try other therapies, he should not be referred. Patients should then have their cardiovascular risk profile assessed: 1. Low Risk patients: Vardenafil therapy can be initiated without further CV w/u: a. No cardiac history, asymptomatic, 6 weeks previous) f. Mild valvular disease g. CHF NYHA class I 2. Moderate	

			risk patients: Prior to initiation of vardenafil therapy, the primary care provider should document that the patient can achieve >4 METS exercise without ischemia. This assessment can be achieved either through a careful history and physical or treadmill test: a. 4 or more risk factors for CAD b. Isolated insulin-dependent diabetes mellitus without prior history of CAD c. Moderate stable angina (with no active nitrate prescription) d. Recent uncomplicated MI (less than 6 weeks previous) e. CHF NYHA class II f. Clinically evident non-cardiac sequelae of atherosclerotic disease (i.e. peripheral vascular disease or stroke) 3. High-risk patients: These patients should be discouraged from using vardenafil. If the patient is insistent on a trial of vardenafil or the primary care provider is unsure, cardiology consultation should be obtained for cardiac clearance prior to the initiation of therapy: a. Unstable or refractory angina b. Uncontrolled hypertension c. CHF NYHA class III or IV d. Recent MI (	
GA900	SIMETHICONE ORAL LIQUID 40MG/0.6ML	MYLICON	Non-Formulary: no criteria for use	NON-FORMULARY

DE500	SINECATECHINS 15% OINT,TOP	VEREGEN	Sinecatechins 15% Ointment VHA National Criteria for Non-Formulary Use Exclusion criteria (If one is selected, patient is NOT eligible): (1) Immunocompromised patient; (2) Treatment of urethral, intra-vaginal, cervical, rectal or intra-anal human papilloma viral disease; or (3) Application to open wounds. Inclusion criteria: (1) The patient is under the care of a dermatologist, gynecologist, urologist, women???s health provider, or local facility equivalent and meets one of the following conditions: (a) Extensive or severe external genital or perianal warts (both 1 & 2 must be selected for patient to be eligible) (1) A large number (??? 10) of individual warts or warts involving large areas of skin in areas otherwise difficult to treat with typical destructive modalities such as cryotherapy, podophyllin or trichloroacetic acid (2) Documented inadequate response or tolerance to other patient-administered agents (podofilox for at least 4 one-week cycles and imiquimod for at least 4 one-week cycles) (b) Isolated external genital warts (< 10) on penile shaft, glans or vulvar areas or isolated perianal warts (both 1 & 2 must be selected for patient to be eligible) (1) Documented inadequate response or intolerance to at least two of these treatment modalities: topical 0.5% podofilox (at least 4 one-week cycles), podophyllin (25% or higher strength for at least 4 weekly applications), trichloroacetic acid (8% or higher strength for at least 4 weekly applications), and cryotherapy (at least 4 cycles) (2) Documented inadequate response or intolerance to imiquimod (at least 4 one-week cycles). Dosage and administration (Refer to PI for dosage recommendations in organ dysfunction): Topically administered three times per day until complete clearance of all warts (maximum of 16 weeks of therapy); each wart should receive approximately 0.5cm strand of sinecatechins to ensure complete coverage. Recommended monitoring: Tolerability of local adverse effects Patient adherence to dosage regimen. July 2008 VISN 20 P&T Committee	NON-FORMULARY
	SIPULEUCEL-T	PROVENGE	NON-FORMULARY	NON-FORMULARY
HS502	SITAGLIPTIN ORAL TABLET	JANUVIA	Non-Formulary Criteria for Use of DPP-4 Inhibitors (Sitagliptin and Saxagliptin) VHA Pharmacy Benefits Management Service and Medical Advisory Panel FDA approved use: Used as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. It is approved for use as monotherapy or in	NON-FORMULARY

			combination with metformin, sulfonylureas, or thiazolidinediones (TZDs). Combination with insulin is not FDA approved at this time. Exclusion Criteria 0 History of a serious hypersensitivity reaction to sitagliptin or saxagliptin, such as anaphylaxis or angioedema 0 Patients with a history of acute pancreatitis, chronic or recurring pancreatitis and those with a history of pancreatitis secondary to exenatide or another DDPIV inhibitor. Inclusion Criteria1,2 Use as monotherapy (must meet both criteria) 0 Candidate for oral therapy and is intolerant of or has contraindications to use of metformin, sulfonylureas, and pioglitazone 0 Expected change in hemoglobin A1c (A1C) is < 1% in order to reach patient specific goal3 Add-on therapy as part of an oral 2 drug regimen (must meet all 3 criteria) 0 Inadequate glycemic control on monotherapy with metformin (at maximally tolerated dose) or sulfonylurea (at 50% maximal dose or highest tolerated dose), and pioglitazone (at maximally tolerated dose) 0 Unable to tolerate or has contraindications to addition of a 2nd agent from the above mentioned group 0 Expected change in A1C is < 1% in order to reach patient specific goal3 Add-on therapy as part of an oral 3-drug regimen (must meet all 4 criteria) 0 Inadequate glycemic control on combination therapy with any 2 of the following drugs: sulfonylurea, metformin, and pioglitazone 0 Unable to tolerate or has contraindications to addition of a 3rd agent from the above mentioned group 0 Patient is not a good candidate for addition of insulin4 OR Patient declines insulin despite receiving information on pertinent therapeutic options and on his/her target A1c goal as well as on the ability of the various therapeutic options to achieve the desired A1c target goal and/or meet other clinical needs. Counseling should involve the patient's primary care provider(s) and, when feasible, instruction about and demonstration of insulin injection by those with expertise in diabetes care (e.g., diabetes educators, nurses, or other appropriate clinicians). 0 Expected change in A1C is < 1% in order to reach patient specific goal (triple therapy studied with sitagliptin)3 Add-on therapy as part of an oral 4-drug regimen 0 The efficacy and safety of such a combination is not known and should be strongly discouraged. Such a trial might rarely be considered in patients with inadequate glycemic control on 3 drug therapy and who are not good candidates for the addition of insulin. Dosage Refer to Table 1 Special Considerations Refer to Table	

			2 for safety considerations Discontinuation criteria Discontinue if little to no improvement in glycemic (e.g., A1C, postprandial glucose) goals are seen after 3-6 months of therapy 1Insulin may be considered at any time prior to using a DPP-4 inhibitor; however, it should be considered if patient is symptomatic or a greater reduction beyond what is achievable by a DPP-4 inhibitor is desired. 2Patients who are drug therapy naive or have higher baseline A1C values may have a greater reduction in A1C 3Refer to the Va/DoD Diabetes Guidelines http://www.healthquality.va.gov/index.asp for recommendations on individualizing A1C targets 4Type 2 diabetics with special circumstances where the risk of severe hypoglycemia and/or its potential consequences are significant and/or catastrophic (e.g. frail elderly, liver failure, severe renal failure, workers with frequent rotating shifts and occupations such as truck or bus drivers or heavy machinery operators) or patients who are unable to master injection technique. Table 1: Recommended Dose Sitagliptin Recommended daily dose: 100 mg once daily taken without regard to meals Moderate renal impairment: 50 mg once daily CrCl = 30 to 1.7- = 3.0mg/dl [males] SCr >1.5- = 2.5mg/dl [females] Severe renal insufficiency or end-stage renal disease: 25 mg once daily Severe renal impairment (CrCl < 30mL/min or SCr > 3.0mg/dl for males or > 2.5mg/dl for females) ESRD requiring hemodialysis or peritoneal dialysis. Sitagliptin may be administered without regard to time of dialysis. Use with strong CYP 3A4/5 Inhibitors: Not applicable Use with sulfonylureas: When used with a sulfonylurea, a lower dose of the sulfonylurea may be required as hypoglycemia was reported more often in those treated with this combination. Saxagliptin Recommended daily dose: 2.5 or 5 mg once daily taken without regard to meals Moderate renal impairment: 2.5 mg once daily (CrCl = 50ml/min) Severe renal insufficiency or end-stage renal disease: 2.5 mg once daily in ESRD requiring hemodialysis (administer after HD). There are no studies evaluating saxagliptin in patients undergoing peritoneal dialysis. Use with strong CYP 3A4/5 Inhibitors: The dose of saxagliptin is 2.5mg once daily if taken concurrently with a strong CYP3A4/5 inhibitor. No dosage adjustment is necessary if taken with inducers or moderate inhibitors of CYP3A4/5 enzymes. Use with sulfonylureas: When used with a sulfonylurea, a lower dose of the sulfonylurea may be required as	

			hypoglycemia was reported more often in those treated with this combination. Table 2: Special Considerations Serious allergic and hypersensitivity reactions There have been post-marketing reports of serious allergic and hypersensitivity reactions (e.g. anaphylaxis, angioedema, exfoliative skin conditions including Stevens-Johnson syndrome) with sitagliptin. If these reactions occur, discontinue agent and initiate alternative treatment for diabetes. It is unknown at this time if saxagliptin carries the same risk; therefore, the above precautions should be followed. Pancreatitis There have been reported cases of acute pancreatitis, including hemorrhagic or necrotizing pancreatitis with sitagliptin. Sitagliptin has not been studied in patients with a history of pancreatitis; therefore, it is unknown whether these patients are at an increased risk for developing pancreatitis. It is unknown at this time if saxagliptin carries the same risk; therefore, the following precautions should be followed. Monitor patients carefully for the development of pancreatitis after initiation or dose increases of agent. Discontinue agent if pancreatitis is suspected while using these products. VISN 20 P&T Committee January 2010 .	
HS502	SITAGLIPTIN/METFORMIN ORAL TAB	JANUMET	Sitagliptin/metformin combination product (NF) is available for patients stabilized on both medications. Sept 2007 VISN 20 P&T	NON-FORMULARY
TN401	SODIUM FERRIC GLUCONATE	FERRLECIT	Restricted to patients with documented intolerance, such as anaphylactoid reaction, to iron dextran. Oct 2000	NON-FORMULARY
MS900	SODIUM HYALURONATE (HYALGAN) INJ	HYALGAN	Synvisc and Hyalgan are non-formulary, restricted to Rheumatology and Orthopedics Services for the treatment of pain in osteoarthritis (OA) of the knee in patients who meet the following national criteria: VA National Criteria for Non-Formulary Use of Hylan G-F 20 (Synvisc) and Sodium Hyaluronate (Hyalgan): Intra-Articular Administration for Osteoarthritis of the Knee The intra-articular (IA) administration of hyaluronic acid or hylan (cross-linked hyaluronan chains) is referred to as viscosupplementation. There are currently five products available in the US. These products are categorized as Biologic Devices by the FDA and can be considered for use in patients with OA of the knee who meet the following criteria. It is strongly recommended that the use of these agents be limited to specialists in Orthopedics, Rheumatology and Physical Medicine and Rehabilitation. (For details, refer to the	NON-FORMULARY

			hyaluronan/hylan review at www.pbm.va.gov or http://vaww.pbm.va.gov). EXCLUSION CRITERIA (If one is selected, patient is not eligible) o Known hypersensitivity or allergy to hyaluronate preparationsa o Knee joint infection, skin disease or infection in the area of the injection site a Orthvisc is contraindicated in patients with an allergy to avian proteins, feathers or eggs. INCLUSION CRITERIA (All must be selected for patient to be eligible) o Documented symptomatic (pain/stiffness) OA of the knee which interferes with functional activities (e.g. ambulation, prolonged standing, etc.) and/or is associated with significant pain. o Adequate trial (e.g. 2 to 3 months) of non-pharmacologic measures, as appropriate, (e.g. cane/crutches, bracing/orthotics, weight loss, physical therapy/exercise) has not resulted in adequate improvement in pain/function o Therapeutic trial of at least 3 analgesics (e.g. acetaminophen, topical capsaicin or topical NSAIDs, oral NSAIDs and other oral analgesics [e.g. tramadol] or narcotic analgesics [in patients with severe pain]) has not resulted in adequate improvement in pain/function; or patient is unable to tolerate or is not a candidate for NSAIDs or other oral analgesics. o Intra-articular corticosteroids have not resulted in adequate improvement in pain/function or there are compelling reasons to avoid IA corticosteroids. o Patient and/or provider have elected to continue conservative (nonsurgical) treatment for OA. PRECAUTIONS o There is some evidence to suggest that patients with more advanced stages of OA and near complete loss of joint space may be less likely to benefit from this therapy. o All HA or Hylan products are for intra-articular use only. o The origin of hyaluronic acid for Hyalgan, Orthovisc, Supartz and Synvisc is from avian sources (rooster combs). Labeling for Hyalgan, Supartz and Synvisc suggest administering with caution in those patients with a known allergy to avian proteins, feathers or eggs. However, Orthovisc is contraindicated in these individuals. Euflexxa is not derived from avian sources and can be used in patients with an allergy to avian proteins. o The safety/efficacy of concomitant administration of IA HA or hylan with other IA agents has not been established. o The safety/efficacy of administering these agents in pregnant women has not been established. DOSAGE AND ADMINISTRATION o Inta-articular administration of HA or hylan should be performed by a physician/provider who is technically	

			proficient at administering drugs via the IA route. o Strict aseptic administration technique must be used. o Disinfectants containing quaternary ammonium salts (e.g. benzalkonium chloride or benzethonium chloride) should not be used for skin preparation as hyaluronic acid can precipitate under such conditions. May use isopropyl alcohol or povidone-iodine solutions to thoroughly clean site. o Remove joint effusion, if present, before injecting HA or hylan. o Subcutaneous lidocaine or other local anesthetic may be injected prior to IA administration of HA or hylan. Euflexxa Hyalgan Orthovisc # Inject/Course 3 3 or 5 3 or 4 Response 3 months* 3 inj-60 days* 6 months 5 inj- 6 months Supartz Synvisc Synvisc-One # Inject/Course 3 or 5 3 1 Response 3 inj-90 days* 5 inj- 6 months 6 months 6 months *Duration of study follow-up RECOMMENDED MONITORING/PATIENT INFORMATION o Transient pain and/or swelling of the injected joint have been reported after intra-articular administration of these agents. o As with any invasive procedure, it is recommended that patients avoid strenuous activity (e.g. more than 1 hour) or prolonged weight-bearing activities (e.g. jogging or tennis) within 48 hours of procedure. o Rare, anaphylactoid/allergic reactions have been reported with Hyalgan o Pseudosepsis or severe acute inflammatory reactions (SAIR) has been reported with Synvisc. Typically with the second or third injection in a course or with subsequent courses. REPEAT COURSES o There is evidence to support administering repeat courses of Hyalgan or Synvisc in those patients having experienced a beneficial response with their first course. However, the risk for adverse events does appear to increase in those given repeat courses with Synvisc but not Hyalgan. There is limited safety data for repeat Synvisc-Oner courses. The efficacy/safety of giving repeat courses using the other available products has not been established. o Repeat courses should not be administered within 6 months of the last injection. VISN 20 P&T Committee Jan 2010 .	
CN000	SODIUM OXYBATE	XYREM	Non-Formulary, Restricted to the treatment of uncontrolled cataplexy in patients with narcolepsy who have not responded to alternative therapy. VA National procurement and distribution procedures must be followed. July 2004	NON-FORMULARY

GA202	SODIUM PHOSPHATE/BIPHOSPHATE ORAL LIQUID	FLEETS PHOSPHO-SODA	Non-Formulary: no criteria for use	NON-FORMULARY
AD400	SODIUM POLYSTYRENE SULFONATE POWDER	KAYEXALATE	Non-Formulary: no criteria for use	NON-FORMULARY
CV600	SODIUM TETRADECYL SULFATE INJ	SOTRADECOL	Non-Formulary: no criteria for use	NON-FORMULARY
PH000	SODIUM THIOSULFATE CRYSTALS	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
AN900	SORAFENIB	NEXAVIR	NON-FORMULARY	NON-FORMULARY
AN900	SORAFENIB ORAL TAB	NEXAVAR	Sorafenib is non-formulary, restricted to VA Hematology/Oncology staff or local VA facility equivalent to the following criteria for use: Sorafenib is one choice for first-line therapy of advanced renal cell carcinoma in patients whose disease is unresectable. It is also appropriate as a second-line agent in patients who have progressed following 1 prior therapy for metastatic disease. (a) Other criteria for use of sorafenib include adequate baseline organ functions (e.g., CrCl > 30 ml/min, ALT and ASt < 2.5 times ULN, and bilirubin < 1.5 times ULN) and (b) Evaluable disease (either measurable disease or number of metastatic sites or evaluable symptoms). Sorafenib Exclusion Criteria: (a) Symptomatic coronary artery disease or ischemia (b) Brain metastases, meningeal metastases (c) Child-Pugh C Hepatic Impairment Sorafenib Discontinuation: Sorafenib therapy should be discontinued when there is evidence of disease progression (new metastatic sites, progression of symptoms, increase in measurable tumor size > 25%) OR patient has intolerable toxicity. July 2006 VISN 20 P&T Committee	NON-FORMULARY
OR100	STANNOUS FLUORIDE GEL, FOAM, LIQUID AND VARNISH	N/A	Non-Formulary: no criteria for use	NON-FORMULARY

MS400	SULFINPYRAZONE 200MG CAP	ANTURANE		NON-FORMULARY
			FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	
CN105	SUMATRIPTAN SUCCINATE NASAL	IMITREX	VISN 20 5HT-1D (serotonin) receptor agonist (triptan) Criteria: SUMATRIPTAN oral tabelts are open formulary, first line Zolmatriptan is formulary, second line, reserved for patients intolerant to sumatriptan oral tablets Naratriptan is non-formulary, second line, reserved for patients who cannot be successfully treated with sumatriptan or zolmitriptan. January 2010 VISN 20 P&T The following has useful information, but no represent longer current restrictions. PREVIOUS VISN SUMATRIPTAN CRITERIA FOR USE 1) Sumatriptan, a 5HT-1D (serotonin) receptor agonist, is approved only for treatment of classic and common migraine. It is not used for basilar or hemiplegic migraine headaches. 2) Generally, the first dose should be given under medical supervision. If the first dose is given outside the VA, there should be some notification and documentation of the effectiveness of sumatriptan. 3) Patients can receive sumatriptan from a provider if NSAIDS, ergotamine, or dihydroergotamine (DHE) therapy have been shown to be ineffective or not tolerated. 4) Patients should not get sumatriptan if there is a contraindication such as ischemic heart disease (angina, history of MI, documented silent ischemia), Prinzmetal's angina, uncontrolled hypertension, pregnancy or women trying to get pregnant, or hypersensitivity. In addition, sumatriptan should not be used concomitantly with ergot-containing preparations. 5) Sumatriptan has many potential adverse effects including: dizziness; flushing; nasal discomfort; pressure sensations throughout the body; taste disturbances; nausea; myocardial infarction; arrhythmias; renal failure; CVA; and angina. 6)	NON-FORMULARY

			Administration, dosing, and cost of individual dosage forms: A. Sumatriptan Injectable (6mg injection - $24.81 each) 1. Suggested dosage: One 6mg injection SC at start of headache may repeat in 1 hour if needed. Manufacturer states that if the first injection provides NO relief, then a second injection is unlikely to be of benefit. 2. No more than 12mg (2 injections) per headache. 3. Sumatriptan injectable will be limited to the treatment of 4 headaches per month (8 syringes per month). Monthly cost is $198. B. Sumatriptan Oral (25mg tablet - $6.62 each) (50mg tablet - $7.56 each) 1. The recommended dosage is 25-50mg at the start of migraine. Subsequent 25-50mg doses may be taken at least 2 to 4 hours after each previous dose, if needed. 2. No more than 200mg in a 24 hour period per headache. 3. Sumatriptan oral will be limited to the treatment of 4 headaches per month (16 doses per month). Monthly cost is $106 (25mg tablet) or $121 (50mg tablet). C. Sumatriptan Nasal Spray (20mg dose - $10.36 each) 1. Improved efficacy over oral formulation. 2. Recommended dosage is one 20mg spray in one nostril, may repeat in 2 hours. 3. No more than 40mg (2 doses) in a 24-hour period. 4. There is evidence that taking doses larger than 20mg does not increase efficacy. 5. Sumatriptan nasal spray will be limited to 4 migraines per month (8 doses per month). Monthly cost is $83. D. Efficacy Rates Drug Efficacy Rate Sumatriptan injectable 70% Sumatriptan nasal spray 64% Sumatriptan oral (all doses) 54% 7) Sumatriptan is contraindicated in patients with hepatic insufficiency and renal failure. 8) In patients exhibiting one or more of the following risk factors, sumatriptan dosage will not be increased: hypertension; strong family history of CAD; hypercholesterolemia; obesity; post-menopausal women; diabetes; smoker; males > 40 years; and any other causes of headache. 9) In patients where more than 8 doses for injectable or nasal spray or 16 doses for oral per month are desired, another route of administration of sumatriptan should be tried. If all forms of therapy have been tried, a non-formulary drug request must be submitted and approved by Neurology Service or local medical center equivalent specialist prior to dispensing. 10) All patients requiring more than 8 doses for injectable or nasal spray or 16 doses for oral per month should be reviewed for use of migraine prophylactic medications to include one or more of the following: divalproex (Depakote); propranolol (Inderal); amitriptyline (Elavil);

			or verapamil (Calan).	
AN900	SUNITINIB ORAL CAPSULE	SUTENT	Sunitinib is Non-Formulary, restricted to Hematology/Oncology staff or local facility equivalent, available for use in patients with GIST and metastatic renal cell carcinoma according to the following national criteria for use: (1) GIST: For patients with GIST who are intolerant of or resistant to imatinib therapy and are not amenable to curative surgical procedures, sunitinib is the only choice currently available for therapy. Assessment of baseline cardiac function and ongoing monitoring of cardiac function will be important in the general population. (2) Metastatic Renal Cell Carcinoma: At this time, differentiation of sunitinib and sorafenib in MRCC has not been determined. Until we can determine the best populations for each drug, sunitinib inclusion criteria include: (a) Patients with metastatic renal cell carcinoma, either first-line or following failure on cytokine based therapy. (b) For all patients, careful consideration should be given to obtaining a baseline evaluation of ejection fraction. Sunitinib is not recommended for patients with any cardiac history. Close monitoring of cardiac function is recommended for patients with any risk factors for cardiac disease. (c) Patient with adequate hepatic, renal, and hematologic values at baseline. Patients with brain metastases should be excluded. Discontinuation: Patients with progressive disease or unacceptable toxicity. January 2007 VISN 20 P&T Committee	NON-FORMULARY
DE300	SUNSCREEN-29 PABA-FREE COMBINATION LOTION (OTC)	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
DE900	SUTILAINS TOP OINT	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
CN900	TACRINE HCL ORAL	COGNEX		NON-FORMULARY
DE802	TACROLIMUS TOPICAL OINT	PROTOPIC		NON-FORMULARY
GU900	TAMSULOSIN ORAL	FLOMAX	National Non-Formulary Criteria for Use Clinically Uroselective Alpha1-Adrenergic Blockers in VA Patients with Benign Prostatic Hyperplasia INCLUSION CRITERIA FOR TAMSULOSIN (Must have at least ONE of the following to be eligible) - Significant symptomatic hypotension, orthostatic or postural hypotension, or syncope or near syncope while on a VA National	NON-FORMULARY

			Formulary (VANF) alpha1-blocker - Significant adverse event attributed to a VANF alpha1-blocker after consideration of decrease in dose or trial of alternate VANF alpha1-blocker - Baseline significant orthostatic or postural hypotension symptoms prior to treatment with a VANF alpha1-blocker - Patients with concomitant hypertension (HTN) and BPH who are being treated with antihypertensive therapy in addition to a VANF alpha1-blockere, who develop symptomatic hypotension (despite adjustment of VANF alpha1-blocker or antihypertensive therapy) or who develop inadequate control of Lower Urinary Tract Symptoms (LUTS) after adjustment of VANF alpha1-blocker to avoid hypotension - Conditions that do not allow adequate time for titration with an alpha-blocker (e.g., urinary stone passage, acute urinary retention, for bothersome LUTS immediately following brachytherapy of prostate) notes: a - The change in blood pressure with terazosin has been found to be clinically insignificant in BPH patients who are either normotensive or have hypertension (HTN) that is well-controlled with pharmacologic agents; patients with blood pressures in the lower range who are asymptomatic should receive a trial of a VANF alpha1-blocker, whenever possible (refer to table of BP lowering effects of terazosin and doxazosin in patients who are normotensive, with or without treatment for HTN) b - Defined as a decrease in SBP > 20 mm Hg upon standing from the supine position, or a decrease in DBP > 10 mm Hg upon standing with DBP < 65 mm	

			Hg, or an increase in pulse of > 20 bpm upon standing with a standing pulse > 100 bpm c - Not related to inappropriate initiation of therapy d - For patients with significant baseline hypotension (not receiving antihypertensive medication), use of an alpha1-blocker should be at the clinician's discretion e - For additional information, refer to http://www.pbm.va.gov/criteria/allhatstatement.pdf or http://vaww.pbm.va.gov/criteria/allhatstatement.pdf f - Antihypertensive agents being used for indications other than HTN (e.g., heart failure, diabetic nephropathy, angina, cardiac arrhythmias, etc) may not be appropriate for modification DOSING RECOMMENDATIONS o Tamsulosin is available as a 0.4mg capsule that is to be administered 30 minutes after the same meal once daily; the capsules should not be chewed, crushed, or opened o Since doses of tamsulosin greater than 0.4mg have not been found to be consistently more effective and may result in increased adverse effects (e.g., dizziness, orthostatic hypotension, abnormal ejaculation), it is recommended that patients prescribed doses greater than 0.4mg daily be reevaluated for efficacy (e.g., per AUA/IPSS*) and tolerability, and the dose lowered if appropriate MONITORING o Due to the risk for symptomatic postural hypotension, dizziness, or syncope, patients should be instructed to avoid situations where injury may result if syncope occurs upon initiation of therapy. In addition, patients should be queried as to whether they experienced a fall while on treatment o Ejaculatory disorders have been reported with

			tamsulosin, especially at higher doses o Tamsulosin has rarely been associated with priapism and patients should be informed as to the seriousness of this condition o Due to the potential for significant hypotension with concomitant administration of an alpha1-blocker and PDE5 inhibitor (e.g., vardenafil), patients should be on a stable dose of their alpha1-blocker or PDE5 inhibitor prior to administration of the other agent; start with the lowest recommended dose and titrate based on response and tolerability. In addition, it is recommended that simultaneous administration be avoided to reduce the potential for hypotension o During cataract surgery, the occurrence of Intraoperative Floppy Iris Syndrome (IFIS) has been observed in some patients receiving or previously treated with an alpha1-blocker. Product information for tamsulosin includes a recommendation that ophthalmologists should be aware of those patients receiving treatment with an alpha1-blocker in order to prepare for potential surgical modifications that may be required RECOMMENDATIONS FOR DISCONTINUATION o Patient does not experience an improvement in LUTS* o Patient experiences significant drug related adverse event; if an intolerable side effect occurs with tamsulosin, alfuzosin may be considered (refer to the National PBM Drug Monograph for Alfuzosin at http://www.pbm.va.gov/monograph/Alfuzosin.pdf or http://vaww.pbm.va.gov/drugmonograph/Alfuzosin.pdf for therapeutic considerations and recommendations for dosing and monitoring)

			VISN 20 P&T Committee January 2008	
CN101	TAPENTADOL	NUCYNTA	NON-FORMULARY	NON-FORMULARY
CN101	TAPENTADOL TAB	NUCYNTA	Non-Formulary: no criteria for use	NON-FORMULARY
GA900	TEGASEROD ORAL TAB	ZELNORM	VA National Criteria for Non-Formulary Use of Tegaserod Adapted by VISN 20 January 2006 #1 Exclusion Criteria O Treatment of idiopathic chronic constipation for patients age 65 or older O Treatment of constipation predominant irritable bowel syndrome (IBS) in men O Chronic idiopathic constipation due to pelvic floor dysfunction O IBS with alternating symptoms of constipation and diarrhea O Diarrhea predominant IBS O Treatment of diabetic gastroparesis* O Treatment of GERD O Chronic constipation induced by medications or caused by other co-morbid conditions O CrCl < 15 ml/min/1.73m2 If Yes to any of these conditions, patient is ineligible to receive tegaserod *???Exceptions to these exclusion criteria should be adjudicated on a case-by-case basis through the non-formulary process.??? ---------- #2 Inclusion Criteria Tegaserod should only be used for patients who do not meet the exclusion criteria above and who have one of the following diagnosis: O Treatment of idiopathic chronic constipation for patients under the age of 65 years who have documented failure of all current formulary agents (agents listed in cost section of Drug Monograph). Non-formulary request should come from a GI specialist or other designated person with expertise in this area. O Short-term treatment of constipation predominant irritable bowel syndrome in women ??? If yes (and no for #1), patient is eligible to receive tegaserod ---------- #3 Dosing O Constipation predominant IBS: The recommended dose is 6mg taken twice daily before meals for 4-6 weeks. For patients who respond to therapy during this time period, an additional 4-6 weeks of treatment can be considered. O Treatment of idiopathic chronic constipation: The recommended dose is 6mg taken twice daily before meals. The patient must be limited to a 30-day supply with no refills. O Efficacy beyond 12 weeks has not been substantiated by clinical trials. O Tegaserod should be taken 30 minutes prior to meals. O Reassessment for efficacy by documenting symptom and/or quality of life improvement in the patient???s medical record is needed for continued use ---------- #4 Monitoring O Constipation predominant IBS:	NON-FORMULARY

			Patients should be reevaluated after 4-6 weeks to document any significant improvement. For patients who respond to therapy during this time period, an additional 4-6 weeks of treatment can be considered. O Treatment of idiopathic chronic constipation: Patients should be reevaluated after a 30 day trial. The patient must keep a daily report of stool frequency or other data deemed relevant by prescriber. A new consult must be provided for further refills. Discontinuation Criteria O No documented symptom relief after 4 weeks: abdominal pain or discomfort O No documented constipation relief after 4 weeks: change in frequency, consistency or form of stool January 2006 VISN 20 P&T Committee	
AM800	TELAPREVIR	INCIVEK	NON-FORMULARY, CFU	NON-FORMULARY
AM900	TELAVANCIN INJ	VIBATIV	Non-formulary Recommendations for Use of Telavancin (Vibativ) May 2010 Pharmacy Benefits Management Services, Medical Advisory Panel and VISN Pharmacist Executives The following recommendations are based on current medical evidence. The content of the document is dynamic and will be revised as new clinical data become available. The purpose of this document is to assist practitioners in clinical decision making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician, however, must make the ultimate judgment regarding the propriety of any course of treatment in light on individual patient situations. For details, refer to Telavancin Monograph and Document Recommendations for Use of New Gram-Positive Agents at http://vaww.pbm.va.gov. FDA APPROVED INDICATION(S) FOR USE Complicated skin and skin structure (cSSSI) infections in adults caused by susceptible Gram-positive bacteria EXCLUSION CRITERIA (If one is selected, patient is NOT eligible) Safety O Known hypersensitivity to telavancin or vancomycin O Pregnancy (Unless benefits outweigh risks; refer to boxed warning in product labeling; Pregnancy Category C) O Patients with congenital long QT syndrome, known prolongation of the QTc interval (QTc >500msec), uncompensated heart failure, or severe left ventricular hypertrophy. O Patients receiving injectable anticoagulants (e.g., heparin, low molecular weight heparin, direct thrombin inhibitors) who need or who are predicted to need frequent (i.e., more than once per day) laboratory monitoring by activated partial	NON-FORMULARY

			thromboplastin time, coagulation based factor Xa tests, or activated clotting time. Microbiological O Clinical evaluation of patient with positive microbiology culture (s) is consistent with colonization (not active infection). O Known resistance to telavancin CAUTION In a subgroup analysis of the pooled cSSSI studies, clinical cure rates in the telavancin treated patients were lower in patients with baseline CrCl =50 mL/min compared to those with CrCl >50 mL/min. A decrease of this magnitude was not observed in vancomycin-treated patients. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate/severe renal impairment. INCLUSION CRITERIA MRSA Infection (Select all boxes within MRSA infection to be eligible O Documented complicated skin and skin structure infection caused by MRSA. O Unable to utilize vancomycin due to intolerance (i.e., serious adverse drug reaction), in vitro non-susceptibility, or infection unresponsive to vancomycin despite therapeutic vancomycin concentrations. O Unable to utilize alternative anti-MRSA agents (i.e., daptomycin, linezolid) or oral agents (e.g., TMP/SMX, minocycline, doxycycline, clindamycin, linezolid). Safety For patients receiving anticoagulants (e.g., warfarin, heparin, low molecular weight heparin, direct thrombin inhibitors) who are receiving once per day laboratory monitoring by tests that telavancin interferes with the results (Select this box to be eligible), O Obtain blood samples for testing prothrombin time, international normalized ratio, activated partial thromboplastin time, activated clotting time, and/or coagulation based factor Xa tests within 6 hours prior to patient's next dose of telavancin (preferably as close as possible prior to a patient's next dose of telavancin). For women of childbearing potential (Select both boxes to be eligible), O Serum pregnancy test should be performed prior to administration of telavancin. O Use of an effective method of contraception during telavancin therapy DOSAGE AND ADMINISTRATION (Refer to PI for dosage recommendations in organ dysfunction) 10 mg/kg administered over 60 minutes by intravenous infusion once every 24 hours Renal dosage adjustment is recommended for patients whose creatinine clearance is =50 mL/min RECOMMENDED MONITORING -Monitor renal function (i.e., serum creatinine, creatinine clearance) in all patients receiving telavancin. Values should be obtained prior to initiation	

			of treatment, during treatment (at 48 to 72-hour intervals or more frequently, if clinically indicated), and at the end of therapy. If renal function decreases, the benefit of continuing telavancin versus discontinuing and initiating therapy with an alternative agent should be assessed. ISSUES FOR CONSIDERATION - Telavancin does not interfere with coagulation; however, it interferes with certain tests (i.e., prothrombin time, international normalized ratio, activated partial thromboplastin time, activated clotting time, and coagulation based factor Xa tests) used to monitor coagulation when these samples are drawn 0 to 18 hours after telavancin administration for patients being treated once every 24 hours. Blood samples for these coagulation tests should be collected as close as possible prior to a patient's next dose of telavancin. - Hydroxypropyl-beta-cyclodextrin is excreted in urine and may accumulate in patients with renal impairment. Serum creatinine should be closely monitored and, if renal toxicity is suspected, an alternative agent should be considered -Telavancin should be infused over 60 minutes; rapid infusion may be associated with infusion related reactions including flushing of the upper body, urticaria, pruritus, or rash. -In a study involving healthy volunteers, telavancin prolonged the QTc interval. Caution is warranted when prescribing telavancin to patients taking drugs known to prolong the QT interval. Use of telavancin should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy. Patients with these conditions were not included in clinical trials of telavancin. - Telavancin interferes with the urine qualitative dipstick protein assays and quantitative dye methods (i.e. pyrollate red-molybdate). However, microalbumin assays are not affected. June 2010 VISN 20 P&T	
GA103	TELBIVUDINE ORAL TABLET	TYZEKA	Non-Formulary: no criteria for use	NON-FORMULARY
CV805	TELMISARTAN AMLODIPINE	TELMISARTAN AMLODIPINE	NON-FORMULARY	NON-FORMULARY
AN100	TEMOZOLOMIDE ORAL CAP	TEMODAR	Temozolomide (Temodar) is non-formulary, restricted to Oncology, Neurosurgery, or local facility equivalent for patients with refractory anaplastic astrocytoma or other appropriate malignancies who cannot tolerate or who have failed other conventional therapies.	NON-FORMULARY
GU300	TERCONAZOLE 0.4% CREAM,VAG	TERAZOL	Non-Formulary: no criteria for use	NON-FORMULARY

HS600	TERIPARATIDE	FORTEO	Teriparatide Non-Formulary Usage Criteria 1. Treatment of postmenopausal women with osteoporosis (BMD > -2.5 SD T-score) who are at high risk for fracture as defined by: . a. at least one osteoporotic fracture and a subsequent fracture while on oral bisphosphonate therapy, OR . b. multiple risk factors for fracture and a spine or hip (femoral neck) BMD > -3.5 SD T-score despite oral bisphosphonate therapy, OR . c. intolerance to oral bisphosphonates 2. To increase bone mass in men with primary or hypogonadal osteoporosis (BMD >-2.5 SD T-score) who are at high risk for fracture as defined by: . a. at least one osteoporotic fracture and a subsequent fracture fracture while on oral bisphosphonate therapy, OR . b. multiple risk factors for fracture and the spine or hip (femoral neck) BMD > -3.5 SD T-score despite oral bisphosphonate therapy, OR . c. intolerance to oral bisphosphonates 3. All patients treated with teriparatide therapy should also receive 1,000 mg/day calcium and 400 IU/day vitamin D for maximum benefit. July 18, 2003	NON-FORMULARY
HS900	TESAMORELIN	EGRIFTA	NON-FORMULARY	NON-FORMULARY
HS100	TESTOSTERONE TOPICAL GEL	ANDROGEL	Non-Formulary: no criteria for use	NON-FORMULARY
IM200	TETANUS TOXOID INJ 0.5ML	N/A	Non-Formulary: no criteria for use	NON-FORMULARY

MS205	TETRABENAZINE ORAL CAP	XENAZINE	VA National Nonformulary Criteria for Use: Tetrabenazine (Xenazine) PBM/MAP October 2009 EXCLUSION CRITERIA (If one is selected, patient is not eligible) o patient who is actively suicidal o patient with untreated or inadequately treated depression o patients receiving MAOI's o patient receiving reserpine o patients with hepatic impairment o patients with abnormal QTc (>450 ms for males, >470 ms for females) o patient with liver function test outside the normal range in the previous 6 months INCLUSION CRITERIA Huntington's Disease o Patients with disabling or painful chorea Hyperkinetic Movement Disorders Patient with Tardive dyskinesia or dystonia And Has an inadequate response to conventional therapy. Tardive Dyskinesia: Removal of offending agent (i.e. antipsychotic) without resolution of hyperkinetic movement after 3 months Inability to remove offending agent given underlying psychiatric disease Dystonia: No response or are intolerant to alternative agents (local botulinum toxin injections, anticholinergics therapy and/or benzodiazepenes And Has severe, symptomatic dyskinesia that interferes with quality of life, activities of daily living or other measures of disability Efficacy of therapy should be assessed when stable, at one month and at three months. Patients may be followed with AIMS scores or other clinically appropriate measures. Documentation of response should be kept in the patient chart ISSUES FOR CONSIDERATION Following treatment interruption of more than 5 days tetrabenazine therapy should be retitrated when resumed. For short-term treatment interruption of less than 5 days, treatment can be resumed at the previous maintenance dose without titration Use caution when prescribing a strong CYP2D6 inhibitor (eg, fluoxetine, paroxetine, quinidine) to a patient already receiving a stable dose of tetrabenazine. In patients receiving coadministered strong CYP2D6 inhibitors, the daily dose of tetrabenazine should be halved. ... Cost information: cost/patient/year $15,000 - $45,000, depending on dose, per PBM monograph Nov 2009 VISN 20 P&T Committee .	NON-FORMULARY

OP700	TETRACAINE HCL OPH OINT	PONTOCAINE	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
GA700	THIETHYLPERAZINE MALEATE ORAL	TORECAN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CN701	THIOTHIXENE INJ	NAVANE	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

	THROMBOPOIETIN AGONISTS	ELTROMBOPAG AND ROMIPLOSTIM	NON-FORMULARY, CFU	NON-FORMULARY
DX900	THYROTROPIN ALFA 0.9MG/ML INJ	THRYOGEN	Restricted to Endocrinology or local equivalent	NON-FORMULARY
CN400	TIAGABINE ORAL	GABITRIL	Tiagabine is non-formulary, restricted to neurologists, for patients who have failed first line medications for partial seizures (phenytoin and carbamazepine). May 2007	NON-FORMULARY
BL700	TICLOPIDINE HCL ORAL	TICLID	Restricted to Cardiology Service for Cardiac Stents, and Restricted to the prevention of thromboembolic events in patients who are: post-MI or post-stroke, or for patients with peripheral arterial disease who fail therapy with aspirin and clopidrogel or who have intolerable side effects or contraindications to the use of aspirin and clopidrogel. Ticlopidine is third line after aspirin and clopidrogel. July 1998, July 2004	NON-FORMULARY
AM250	TIGECYCLINE	TIGECYCLINE IV	FORMULARY, CLINICAL RECOMMENDATION	NON-FORMULARY
AP109	TINIDAZOLE ORAL TAB	TINDAMAX	Non-Formulary: no criteria for use	NON-FORMULARY
BL300	TISSEEL FIBRIN SEALANT KIT 2ML	TISSEEL	Tisseel Fibrin Sealant Kit is non-formulary, restricted to Neurosurgery as a hemostatic agent, sealant, or mechanical barrier in surgeries requiring repair of dural openings (i.e., CSF leaks) based on the expertise/judgment of the attending surgeon. May 2007	NON-FORMULARY
MS190	TOCILIZUMAB	ACTEMRA	NON-FORMULARY, CFU	NON-FORMULARY
HS502	TOLAZAMIDE 100MG, 250MG TAB	TOLINASE	Non-Formulary: no criteria for use	NON-FORMULARY
GU201	TOLCAPONE ORAL	TAZMAR	Tolcapone is non-formulary, restricted to a neurologist or local facility equivalent who is experienced in treating Parkinson's disease and the side effects associated with tolcapone. The prescriber will be responsible for documenting appropriate consent information in the patient's medical records and for the appropriate laboratory monitoring required for this drug. If no improvement is seen within three weeks of therapy, tolcapone should be discontinued.	NON-FORMULARY
MS102	TOLMETIN ORAL	TOLECTIN	Non-Formulary: no criteria for use	NON-FORMULARY
AU350	TOLTERODINE ORAL (REGULAR RELEASE & LA)	DETROL		NON-FORMULARY
HS900	TOLVAPTAN	SAMSCA	NON-FORMULARY	NON-FORMULARY
CN609	TRAMADOL EXTENDED RELEASE TABLET	ULTRAM ER	Non-Formulary: no criteria for use	NON-FORMULARY
BL300	TRANEXAMIC ACID ORAL RINSE	N/A	Restricted to dental service or local facility equivalent for anticoagulated patients or hemophiliacs.	NON-FORMULARY
CV900	TREPROSTINIL	REMODULIN	NON-FORMULARY, CFU	NON-FORMULARY

RE101	TRIAMCINOLONE 100MCG 240D ORAL INHALER	AZMACORT	(1) Mometasone (Asmanex) is formulary, the first line oral steroid inhaler (2) Flunisolide (Aerobid) is formulary, second line. (3) All other oral corticosteroid inhalers are non-formulary. June 16th 2006 VISN 20 P&T Committee	NON-FORMULARY
VT809	TRI-B HOMOCYSTEINE FORMULA (FOLIC ACID, B6, B12)	TRI-B HOMOCYSTEINE FORMULA	Tri-B Homocysteine Formula (folic acid 0.8mg, vitamin B6, vitamin B12) is non-formulary, restricted to patients who have undergone a PTCA. May 2007	NON-FORMULARY
IM900	TRIETHANOLAMINE OTIC LIQUID	CERUMENEX	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
CN701	TRIFLUOPERAZINE INJ	STELAZINE	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

DE890	TRIOXSALEN ORAL	TRISORALEN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
GU300	TRIPLE SULFA VAG CREAM	SULTRIN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
GU300	TRIPLE SULFA VAG TAB	TRISULEN	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

HS502	TROGLITAZONE ORAL	REZULIN	Non-Formulary: no criteria for use	NON-FORMULARY
AN100	URACIL MUSTARD ORAL	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
IM600	USTEKINUMAB INJ	STELARA	Non-Formulary: no criteria for use	NON-FORMULARY
IM100	VARICELLA VIRUS VACCINE INJ	N/A	Non-Formulary: no criteria for use	NON-FORMULARY
BL900	VELAGLUCERASE ALFA	VPRIV	NON-FORMULARY	NON-FORMULARY
CN609	VENLAFAXINE 24 HR SUSTAINED RELEASE ORAL CAP	EFFEXOR XR	VISN 20 Venlafaxine Criteria for Use in Depression Venlafaxine is restricted to third-line status after intolerance or inadequate response to an appropriate trial of at least two first-line antidepressants (including fluoxetine, citalopram, or sertraline). Patients with a clear history of intolerance or inadequate response to two first-line agents in the community prior to seeking care at the VA may be considered for a venlafaxine trial, if clinically appropriate. Patients who transfer their care to the VA and are already on venlafaxine with a good response to the drug may be continued on the agent and will not be required to switch. Immediate release venlafaxine should be used in preference to sustained action venlafaxine tabs. May 2007 VISN 20 P&T Committee, Jan 2009	NON-FORMULARY
AM800	VIDARABINE INJ	VIRA-A	Non-Formulary: no criteria for use	NON-FORMULARY
VT802	VITAMINS FOR MACULAR DEGENERATION - ZINC & OTHER VITAMINS	OCUVITE PRESERVISION	Non-Formulary: no criteria for use	NON-FORMULARY
AM700	VORICONAZOLE ORAL	VFEND	Voriconazole (Vfend) is non-formulary, restricted to Infectious Diseases, Marrow/Solid Organ Transplant staff, or local facility equivalent.	NON-FORMULARY
BL100	WARFARIN (COUMADIN) NA INJ	COUMADIN	Non-Formulary: no criteria for use	NON-FORMULARY
MS400	XXXXX		Non-Formulary: no criteria for use	NON-FORMULARY

CN309	ZALEPLON ORAL	SONATA	Restricted to patients who fail or are intolerant to zolpidem. Zolpidem criteria are: Restricted to Psychiatry/Mental Health Services or local equivalent according to the following protocol: A. Patient selection: Patients must meet one of the following criteria: 1. Treatment of acute insomnia in the frail older patient (>60 y/o) 2. Treatment of acute insomnia in patients with past or present alcohol and/or benzodiazepine abuse, 3. Currently in a PTSD program 4. Younger patients with concurrent medical illness may be considered on a case-by-case basis B. Short-term use only. Pharmacy to dispense a four week supply or less (20 tablets maximum per 30 day prescription). A not to exceed five nights per week schedule is recommended. C. Only two prescriptions for any 12 month period; NO refills D. Patients must be enrolled in a sleep hygiene program E. Patient must have adequate trials of alternate medications: 1. Antidepressant for one month (doxepin, trazodone or others). 2. An antihistamine may be used if an antidepressant is deemed inappropriate 3. Temazepam (or other benzodiazepines) for one month F. Long-term therapy may be approved on a non-formulary basis (as determined by the local facility).	NON-FORMULARY
CN103	ZICONOTIDE INTRATHECAL INJECTION	PRIALT	Non-Formulary Criteria for Use of Ziconotide for Intrathecal (IT) Infusion Facilities should consider using a review committee to evaluate requests to prescribe IT ziconotide. VA Inclusion Criteria Patients who meet ALL of the following criteria may receive intrathecal (IT) ziconotide: 1. Patient is under the care of a VA pain specialist or anesthesiologist who has experience in the management of polypharmacy with IT pain medications and has the resources to provide 24/7 care for problem management. 2. Patient has chronic cancer or noncancer pain 3. Patient has had documented inadequate response, intolerable adverse effects, or contraindication to: a. systemic opioids plus adjuvant agents (e.g., antidepressants and/or antiepileptics) OR IT morphine (maximum tolerated dose not exceeding 15mg/d) OR off-label IT hydromorphone (maximum tolerated dose not exceeding 10 mg/d)2 (in IT or epidural screening or treatment); b. AND IT clonidine; c. AND IT bupivacaine; d. AND a combination of IT analgesics. 4. Patient has or will have an implanted Medtronic SynchroMed EL or SynchroMedII Infusion System, or Simms Deltec CADDMicro External Microinfusion Device and Catheter. 5. For noncancer pain, patient has received psychological evaluation (to	NON-FORMULARY

			help promote good therapeutic outcomes from IT therapy). VA Exclusion Criteria Patients who meet any of the following criteria should NOT receive IT ziconotide: 1. Contraindication to IT ziconotide therapy: a. previous history of psychosis. b. Any other concomitant treatment or medical condition that would render IT administration hazardous (e.g., infection at the microinfusion injection site, uncontrolled bleeding diathesis, spinal canal obstruction that impairs circulation of CSF). c. Concomitant IT chemotherapy. d. Hypersensitivity to ziconotide or formulation components. 2. Active suicidal or homicidal behavior, major uncontrolled depression or anxiety, or serious cognitive deficits. Discontinuation Criteria NO improvement in either pain or functional ability during the first 3 weeks of IT ziconotide therapy. Weigh Risks Versus Benefits 1. Patients with refractory pain will very likely require concomitant therapy with systemic or IT analgesics. Weigh the potential risks and benefits before deciding to use IT ziconotide concomitantly with IT opioids or other IT agents, such as bupivacaine, clonidine, and baclofen. The stability of these analgesics in admixtures is unknown. The efficacy and safety of only ziconotide monotherapy has been evaluated in clinical trials. 2. Consider potential risks versus benefits of using IT ziconotide in patients who do not have timely access to medical facilities, lack family or social support to assist with patient monitoring at home, and would have difficulty adhering to follow-up visits. January 2007	

CN709	ZIPRASIDONE INJ 20MG/ML	GEODON	Ziprasidone IM (Geodon IM) is non-formulary with the following restrictions: (1) For emergent use in patients with agitated psychosis receiving care in an emergency room or on an inpatient floor where the use of an oral antipsychotic is not feasible. (2) For use as a second-line agent to IM haloperidol in patients who are unable or unwilling to take oral medications, or who do not tolerate haloperidol. (3) Until data are available, do not use IM ziprasidone in the setting of non-psychiatric agitation (e.g., substance abuse, delirium in the medically ill, etc.) (4) Ziprasidone (IM or oral) is contraindicated in patients with a known history of QT prolongation (including congenital long QT syndrome), recent acute myocardial infarction, uncompensated heart failure, or a history of cardiac arrhythmias. (5) Ziprasidone should not be administered with medications that have demonstrated QT prolongation. (6) Intramuscular ziprasidone should not be administered concurrently with oral ziprasidone or other antipsychotic medications. (7) Patients at risk for significant electrolyte disturbances should have baseline serum potassium and magnesium measurements. (8) Ziprasidone should be discontinued in patients who are found to have persistent QTc measurements >500 msec.	NON-FORMULARY
CN400	ZONISAMIDE ORAL	ZONEGRAN		NON-FORMULARY
IM100	ZOSTER VACCINE LIVE (OKA/MERCK) INJ	ZOSTAVAX	VA National Criteria for Use Zoster/Shingles Vaccine March 2011 Inclusion Criteria - Patients must meet all of the following criteria to receive zoster vaccine: 0 Age 60 years and older and immunocompetent at the time of vaccination, regardless of whether the patient reports a prior episode of chickenpox or herpes zoster (HZ). This includes persons with chronic medical conditions, unless	NON-FORMULARY

			those conditions are contraindications or precautions; with a prior physician-diagnosed HZ rash (these persons can frequently have recurrences even shortly after the initial episode)1; with leukemia in remission and not treated with chemotherapy (e.g., alkylating drugs or antimetabolites) or radiation for at least 3 months; receiving low- to moderate-dose (less than 20 mg/d of prednisone or equivalent) or short-term corticosteroid therapy (less than 14 days); intranasal, dermal, inhaled corticosteroids; intra-articular, bursal, or tendon injections of corticosteroids; or long-term alternative-day treatment with low to moderate doses of short-acting systemic corticosteroids; receiving low-dose methotrexate (0.4 mg/kg/wk or less), azathioprine (3 mg/kg/d or less), or 6-mercaptopurine (1.5 mg/kg/d or less) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions; with impaired humoral immunity (e.g., hypogammaglobulinemia or dysgammaglobulinemia) 0 Provider has discussed with patient the potential risks and benefits of vaccination, and the results of the	

			Shingles Prevention Study ++ Exclusion Criteria - Patients should not receive zoster vaccine if any of the following criteria are met: 0 Existing evidence of non-immunity to chickenpox (e.g., negative antibody titers)-offer chickenpox vaccine instead (NB: screening and serologic testing for varicella immunity are not recommended) 0 Life-threatening disease likely to limit survival to less than 1 year 0 History of anaphylactic / anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine 0 History of primary or acquired immunodeficiency states including leukemia that is not in remission or that has been treated with chemotherapy or radiation within the previous 3 months; lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; AIDS, other clinical manifestations of human immunodeficiency virus (HIV), and CD4+ count of = 200 cells/µl or = 15% total lymphocytes; or other unspecified cellular immunodeficiency based on clinical or laboratory evidence. For CD4+ count > 200 cells/µl, hematopoietic stem cell transplantation (HSCT), AND recombinant human immune mediators and	

modulators, see Consider Benefits Versus Risks.
0 Receiving immunosuppressive therapy, including high-dose corticosteroids (= 20 mg/d of prednisone or equivalent) lasting 2 or more weeks. This includes patients who have received organ transplants.
0 Active untreated tuberculosis
0 Pregnant or may be pregnant
0 Acute febrile illness
0 Receiving antiviral therapy that inhibits varicella zoster virus replication (e.g., acyclovir, valacyclovir, famciclovir, ganciclovir, foscarnet, cidofovir, etc.), unless these medications can be temporarily discontinued (see under Dosing, Administration, and Storage).
0 Intended use is to treat acute HZ or to prevent postherpetic neuralgia in persons with acute HZ
Consider Benefits Versus Risks
0 AIDS / HIV infection with CD4+ count > 200 cells/µl. Zoster vaccine is recommended for all indications except pregnancy, immunocompromising conditions, and HIV depending on CD4+ count.
Zoster vaccine is specifically contraindicated if the CD4+ count is 200 cells/µl or less or total lymphocytes is 15% or less. There is no data on the use of zoster vaccine in HIV-infected individuals with CD4+ counts greater than

200 cells/uL.
0 Hematopoietic stem cell transplantation (HSCT). Experience is limited. Assess patient's immune status and risk-benefits on a case-by-case basis. If vaccination is decided upon, administer zoster vaccine at least 24 months after transplantation.
0 Receiving recombinant human immune mediators and immune modulators, especially the antitumor necrosis factor agents such as adalimumab, etanercept, and infliximab. The safety and efficacy of concurrent administration of these agents with zoster vaccine are unknown. If it is not possible to administer zoster vaccine before initiation of therapy, assess the patient's immune status and risk-benefits on a case-by-case basis. Otherwise, wait at least 1 month after discontinuing the immune mediator / modulator therapy before administering zoster vaccine.
Dosing, Administration, and Storage
One dose (0.65 ml) by subcutaneous injection.
A booster dose is not FDA-approved.
Timing of administration in special situations:
0 Persons anticipating immunosuppression. Administer zoster vaccine at the first possible visit while immunity is still intact and at least 14-30 days before beginning immunosuppressive therapy, if delay is

			possible. 0 Persons receiving antiviral therapy that inhibits varicella zoster virus replication (e.g., acyclovir, valacyclovir, famciclovir, ganciclovir, foscarnet, cidofovir, etc. Temporarily discontinue these medications from at least 24 hours before administering zoster vaccine to at least 14 days after, if possible. 0 Persons who recently discontinued high-dose corticosteroids. Defer zoster vaccination for at least 1 month after discontinuation of high-dose corticosteroids (20 mg/d or greater of prednisone or equivalent for 2 or more weeks). 0 Persons undergoing hematopoietic stem cell transplantation. If, after a case-by-case risk-benefit assessment, it is decided to administer zoster vaccine, defer zoster vaccination for at least 24 months after transplantation. 0 Persons receiving recombinant human immune mediators and immune modulators, especially the antitumor necrosis factor agents such as adalimumab, infliximab, and etanercept. If, after a case-by-case risk-benefit assessment, it is decided to administer zoster vaccine, defer vaccination for at least 1 month after discontinuation of the immune mediator/modulator therapy. Zoster vaccine must be protected from light. It SHOULD BE STORED FROZEN at an average temperature of -15°C (+5°F)

			or colder until it is reconstituted for injection. Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains an average temperature of -15°C or colder is acceptable for storing zoster vaccine. Zoster vaccine may be stored and/or transported at refrigerator temperature (2° to 8°C, 36° to 46°F) for up to 72 continuous hours prior to reconstitution. Vaccine stored at 2° to 8°C (36° to 46°F) that is not used within 72 hours of removal from -15°C (+5°F) storage should be discarded. The diluent should be stored separately at room temperature (20 to 25°C, 68 to 77°F), or in the refrigerator. THE VACCINE SHOULD BE ADMINISTERED IMMEDIATELY AFTER RECONSTITUTION TO MINIMIZE LOSS OF POTENCY. DISCARD RECONSTITUTED VACCINE IF IT IS NOT USED WITHIN 30 MINUTES. DO NOT FREEZE reconstituted vaccine. Simultaneous Administration with Other Vaccines for Adults Aged 60 Years and Older The FDA-approved product information for zoster vaccine states that zoster vaccine and pneumococcal polysaccharide polyvalent vaccine should not be given concurrently because concomitant use reduces the immunogenicity of zoster vaccine; co-administration did not affect the	

immunogenicity of the pneumococcal vaccine. However, since the clinical relevance of this observation is not known, the CDC states that zoster vaccine and pneumococcal polysaccharide polyvalent vaccine can be co-administered to prevent missed opportunities for zoster vaccination. The VA PBM, NCP, and Public Health recommend that the zoster vaccine and pneumococcal polysaccharide polyvalent vaccine should be administered 4 weeks apart if feasible but may be concomitantly administered to avoid a missed opportunity to provide both vaccines.
Live, attenuated vaccines: No data available. CDC recommends administering zoster vaccine at least 4 weeks before or after another live, attenuated vaccine.1 Trivalent inactivated influenza vaccine. Immunogenicity is not compromised; may administer simultaneously.
Other inactivated vaccines (e.g., Td, Tdap): No data available; according to CDC recommendations,1 zoster vaccine can be given on the same day, any time before or after an inactivated vaccine.
If zoster vaccine is administered simultaneously with another vaccine, each vaccine must be administered in separate syringes at different body sites.
Prepared: July 2008; Updated August 2008; August 2010; March 2011
Contact: Melinda Neuhauser, PharmD,

			MPH, VA Pharmacy Benefits Management Services + Varicella Virus Vaccine Live (Oka / Merck) ++ Shingles Prevention Study (Oxman MN, et al. NEJM 2005;352:2271-84): http://content.nejm.org/cgi/reprint/352/22/2271.pdf 1 Prevention of Herpes Zoster. MMWR 2008. June 6; 57 (RR-5):1-30. Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5705.pdf. Accessed 08 June 2008. 2 MMWR Quick Guide, Recommended Adult Immunization Schedule - United States, October 2007 -September 2008, available at: http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm#print 3 MMWR General Recommendations on Immunization on Immunization Practices (ACIP). January 28, 2011. V olume 60/No 2.	
BL300	ZZAPROTININ 10,000 UNT(1.4MG)/ML INJ	TRASYLOL	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

BL116	ZZAPROTININ 10000 UNT(1.4MG)/ML INJ,200ML	TRASYLOL	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
DE802	ZZCALCIPOTRIENE 0.005% OINT	DOVONEX	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
NT900	ZZCETYLPYRIDINIUM CL 0.07% LOZENGE	CEPACOL	Non-Formulary: no criteria for use	NON-FORMULARY

RE102	ZZMETAPROTERENOL INHL SOLN	ALUPENT	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
RE102	ZZMETAPROTERENOL ORAL INHL	ALUPENT	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY
DE900	ZZPAPAIN 10000UNT/UREA 10% OINT,TOP	ACCUZYME	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY

DE900	ZZPAPAIN/UREA/CHLOROPHYLL SPRAY, TOP	N/A	FDA indications for valganciclovir include: (1) treatment of CMV retinitis in patients with AIDS and (2) prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Since VA transplant centers routinely use valganciclovir in accord with FDA indications, valganciclovir is restricted to Infectious Disease and Transplant Providers and other providers caring for transplant patients or local facility equivalent(s). VISN 20 P&T November 2008	NON-FORMULARY